LONG RECORDING APPARATUS OF MUSCLE ELECTRIC POTENTIAL BY RADIO SYSTEM

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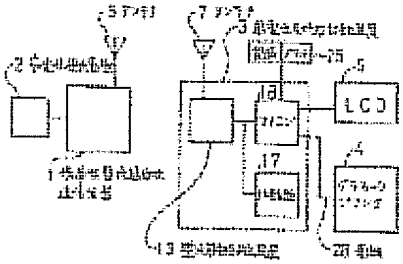
Abstract of JP 7303616 (A)

PURPOSE:To make it possible to measure the muscle activity in the nonrestrained condition and to save the volume of memory and quantity of recording paper to be used. CONSTITUTION:In the subject apparatus, the muscle electric potential detected at the surface of the living body is discharged from the portable muscle electric potential transmitter 1 and received by the long recording apparatus 3 for muscle electric potential built in the microcomputer, and, while the muscle electric potential is measured, the muscle electric potential data over the specified electric pressure and the generating time thereof are taken into the memory, and when the measurement is over, the muscle electric potential is displayed by the analog method and the indices showing the state of muscle activities are computed and printed out. Thereupon, the portable rectifying muscle electric potential transmitter 1 transmits the muscle electric potential detected by the muscle electric potential detective electrode 2 by FM after rectification, and the long recording apparatus 3 for muscle electric potential is composed of a rectifying muscle electric potential reproducing unit 13, a comparator 17 and a microcomputer 18 and receives and demodulates FM signals, takes into the microcomputer 18 the muscle electric potential over the specified electric pressure discriminated by the comparator 17, effects storage and calculations. Then, the muscle electric potential and the various indices of the muscle activities are displayed by the analog method and by the digital method, respectively, on the graphic printer 4.



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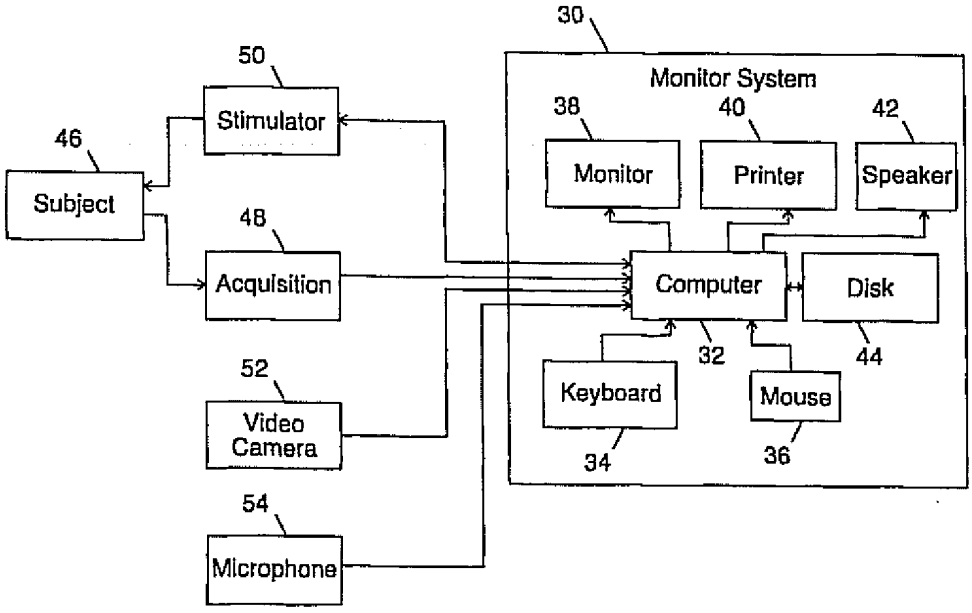

(57) Abstract

The present invention provides a medical signal monitoring system (30), a method for displaying physiological signals of different types, and modalities in different formats on a single system. The monitoring system (30) receives physiological signals from a subject (46) via one or more acquisition systems (48).

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MEDICAL SIGNAL MONITORING AND DISPLAY

FIELD OF THE INVENTION

The present invention pertains generally to medical monitoring equipment, and particularly to methods and devices for analyzing and displaying physiological signals provided by such equipment.

BACKGROUND OF THE INVENTION

Medical monitoring involves monitoring the body of a subject to determine the state of health of the subject and to detect, identify, and diagnosis changes or abnormalities in the state of the body which may be indicative of problems or for treatment evaluation. Medical monitoring may involve, for example, the motion of a subject's body, temperature or chemical changes of the subject's body, and/or audible or electrical signals generated by the subject's body. For example, electroencephalography (EEG) is a form of medical monitoring wherein the electrical potentials of the subject's brain are monitored by attaching electrodes to the subject's scalp. In electromyography (EMG), electrical activity generated in the subject's muscles is monitored using surface and/or needle recording electrodes. Medical monitoring may take place when a subject is at rest, in motion, or during the performance of a medical procedure. In some cases, medical monitoring involves monitoring the response of the subject to a stimulus. For example, evoked potential (EP) monitoring may be used to detect the electrical response of a subject's brain to audible, visual, or electrical stimuli. Medical monitoring involving stimulus and response detection may be used in combination with EMG and various other medical monitoring methods as well.

Monitoring of the various physiological signals generated by a subject's body is typically performed using dedicated devices and/or systems. For

example, EEG monitoring may be performed using a dedicated EEG monitoring system, by attaching electrodes to a subject to detect the electrical potentials of the subject's brain, amplifying and filtering the signals received from the electrodes for the desired frequency range of interest for EEG analysis, and providing the amplified and filtered signals to an EEG analysis system including software for further manipulating the EEG signals for analysis and display on an EEG system monitor. Similarly, EMG monitoring may be performed using a dedicated EMG monitoring system, by placing electrodes on the subject to detect electrical activity generated in the subject's muscles, amplifying and filtering the signals detected by the electrodes for the desired frequency range of interest for EMG signals, and providing the amplified and filtered signals to an EMG analysis system including software for further manipulating the EMG signals for analysis and display on an EMG system monitor. Other signals of interest, e.g., vital signs, may be monitored in a similar manner, with a separate dedicated system provided for each type or modality of monitored signal of interest. Each such dedicated monitoring system may include or be connected to a system for providing stimulus to a subject, and for analyzing the particular detected signal of interest in response to the stimulus provided.

To provide a full range of diagnostic capability, a doctor's office or operating room, ICU or ER must have available systems for monitoring various physiological signals. Thus, EEG, EMG, vital signs, and other physiological signal monitoring systems preferably must be readily available. Where the capability for monitoring each different type of physiological signal is implemented in a dedicated system, maintaining a full range of diagnostic capability can be a very expensive proposition. Moreover, in many cases it may be desirable to monitor the various physiological signals generated by a subject's body simultaneously. Thus, it may be desired to monitor simultaneously EEG, EMG, vital signs, and other physiological signals generated by a subject. If each type of signal to be monitored requires a dedicated monitoring system, each system having its own set of electrodes, monitoring and display units, etc., all simultaneously connected to a subject, an operating room or other medical facility will be crowded with equipment, which

may interfere with the procedures being performed. More significantly, each such system must be operated independently, and may have its own unique user interface. Thus, critical time and effort may be wasted as a physician or other specialist must constantly switch his attention between different medical monitoring systems in order to monitor various physiological signals of interest.

SUMMARY OF THE INVENTION

The present invention provides a medical signal monitoring system and method providing the capability for an operator of the system to display and analyze physiological signals of various types, frequencies, and modalities. The medical monitoring system in accordance with the present invention may be implemented on a conventional computer system having conventional input, output, and disk storage devices. Data input to the medical monitoring system may be provided from various physiological signal acquisition systems, including systems for acquiring electrical physiological signals from electrodes positioned on a subject. Digitized video and audio inputs may also be provided to the medical monitoring system. The medical monitoring system may further be connected to auditory, visual, and/or electrical stimulator systems, for controlling the providing of stimulation to a subject, while analyzing the physiological signals received in response thereto via the acquisition system.

The medical monitoring system in accordance with the present invention employs a data pipeline structure wherein, for example, raw electrical physiological signals from electrodes attached to a subject are both saved and processed. Processing steps which may be performed on the raw electrode signals thus received include defining and generating a signal to be displayed, filtering the signal, defining a trigger signal, averaging the signal, performing spectral analysis and trend calculation of the signal, and displaying the resulting processed signal. Various parameters for each of the processes performed on a signal to be displayed may be established by an operator of the system employing a software user interface implemented in a Windows-type operating system. Since data may be stored as a stream of raw data recorded from an electrode, different signals, having different

modalities and formats, may be generated and displayed from the stored data, to review the data in a different desired context.

In accordance with the present invention, physiological signals of interest are displayed in panels. The user interface allows different panel types to be selected. The panel type selected determines the basic format of the physiological signal to be displayed. Panel formats preferably are provided for displaying physiological signals as various waveforms and/or as indicators, such as bar indicators.

The signals to be displayed in a panel are defined by selecting, via the user interface, the signals provided by a pair of electrodes, from which a montaged pair signal to be displayed is generated. An operator also employs the user interface to select the modality of the signal to be derived and displayed, e.g., EEG, EMG, or evoked potential (EP). The user interface preferably also provides an operator of the system with the option of displaying signals of interest as triggered, averaged, or trend (compressed) data. Triggering, averaging, and spectral trend data parameters are operator selectable employing the user interface.

Various different panels may be defined by an operator for a particular operator's use, or for a particular patient, or physiological monitoring session. The panels as defined and their associated controls and stimulus parameters may be saved as a template.

During acquisition mode data is received into the data pipeline and displayed in the format defined by the panels. Received physiological signals may also be recorded to disk at this time, and played back at a later time, in the format defined by the panels, to review the data. The source of physiological data provided to the system for display may be a physiological signal acquisition system or a physiological data simulator.

The user interface preferably provides various tools for an operator to use during the display of physiological data in a panel. Such tools may include, for example, the ability to attach comments to displayed signals, the use of cursors and markers to measure the amplitude and latency characteristics of a waveform

displayed in a panel, and a look-back tool allowing a portion of a waveform to be frozen for closer examination.

Physiological signals displayed by a medical signal monitoring system in accordance with the present invention may be triggered by stimulus signals provided to a subject via, e.g., electrical, auditory, or visual stimulators. The user interface preferably allows an operator of the system to establish the type of stimulation(s) provided, and the characteristics of such stimulation in a stimulus context. A separate stimulus context may be established for each panel defined by the operator. Stimulus contexts may be different from each other, yet employ the same stimulator rate generators and stimulator systems. Only one stimulus context may be active at a time. A stimulus context is activated by activating a panel. Stimulus context is changed by activating a different panel.

Further objects, features, and advantages of the invention will be apparent in the following detailed description when taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic block diagram of an exemplary medical signal monitoring system in accordance with the present invention.

Fig. 2 is a schematic block diagram illustrating an exemplary interface between signal acquisition and stimulation systems and a medical signal monitoring system in accordance with the present invention.

Fig. 3 is a schematic diagram illustrating a data pipeline employed in a medical signal monitoring system in accordance with the present invention.

Figs. 4-16, 19, and 20 are exemplary screen displays generated by a medical signal monitoring system in accordance with the present invention.

Fig. 4 is a screen display showing an exemplary user interface for a medical signal monitoring system in accordance with the present invention.

Fig. 5 is a screen display showing a pull-down menu of the user interface of Fig. 4, showing different panel types available for displaying signals in different formats in a medical signal monitoring system.

Fig. 6 is a screen display showing a user interface for defining the signals associated to an amplifier device to be displayed in a panel.

Fig. 7 is a screen display showing a user interface for defining digital filtering to be applied to a signal to be displayed.

Fig. 8 is a screen display showing a user interface for defining triggering and averaging parameters for a signal to be displayed.

Fig. 9 is a screen display showing a user interface for defining a trend signal to be displayed.

Fig. 10 is a screen display showing a user interface for defining the general characteristics of a signal to be displayed in a panel.

Fig. 11 is a screen display showing a user interface for selecting a data source to be used during an acquisition mode.

Fig. 12 is a screen display showing examples of panels displaying physiological signal data in different forms.

Fig. 13 is a screen display showing a user interface for finding a comment that was associated with or connected to signals being displayed.

Fig. 14 is a screen display showing the use of cursors for measuring a wave form being displayed.

Fig. 15 is a screen display showing use of markers for measuring a wave form being displayed.

Fig. 16 is a screen display showing use of a look-back function for viewing a portion of a wave form being displayed.

Fig. 17 is a schematic block diagram of available stimulus rate generators and stimulus modalities for an exemplary medical signal monitoring system in accordance with the present invention.

Fig. 18 is a schematic block diagram of an exemplary stimulator context established using the user interface of a medical monitoring system in accordance with the present invention.

Fig. 19 is a screen display showing an exemplary user interface for establishing a stimulator context for a medical monitoring system in accordance with the present invention.

Fig. 20 is an exemplary screen display showing the display of various stimulation triggered physiological signals.

DETAILED DESCRIPTION OF THE INVENTION

The present invention provides an integrated medical signal monitoring system, allowing a physician or other operator to display and monitor simultaneously various different types of physiological signals recorded from a subject. The present invention provides an integrated flexible user interface, which allows an operator of the system to define the manner of interaction and to control the information which will be displayed and analyzed, as well as to control the providing of stimulation to a subject when the determination of the physiological response of a subject to stimulus signals is desired.

A basic hardware configuration for a medical signal monitoring system 30 in accordance with the present invention is illustrated in, and will be described with reference, to Fig. 1. A medical signal monitoring system 30 in accordance with the present invention may be implemented using a conventional computer system having conventional computer peripheral devices. For example, monitoring system 30 may be implemented on a conventional personal computer 32. Due to the large number of computations performed by the computer 32, a computer employing a very fast processor, such as a Pentium 200 MHz processor, or faster, is preferred. It should be understood that the present invention may be implemented using other types of general purpose programmable computers 32.

The computer 32 is preferably provided with conventional computer peripherals. For example, the computer 32 preferably includes conventional input devices such as, for example, a keyboard 34 and a mouse 36. Other types of input devices, such as a microphone for voice recognition control of the system, may be employed. Conventional output devices which may be employed with the computer 32 include a computer monitor 38, printer 40, and speaker 42 for providing audio output from the computer 32. The computer 32 is preferably also provided with a large disk storage capability 44.

The monitoring system 30 receives physiological signals from a subject 46 via one or more signal acquisition systems 48. The signal acquisition systems 48 may be connected to the subject by, for example, electrodes placed on the subject 46. The electrodes provide electrical physiological signals to the acquisition systems 48. The acquisition systems 48 amplify the signals received from the electrodes 46, provide some preliminary filtering of the signals, and then provide the amplified and preliminarily filtered signals to the monitoring system 30 for analysis and display. In a dedicated EEG or EMG system, the acquisition systems 48 may filter the electrode signals to a relatively narrow band of interest. However, the present invention provides a system for the display of signals across a broad frequency range. Thus, a broad band of frequencies should be passed by the acquisition systems 48 (e.g., at least broad enough to include the EEG and EMG bands). The signals provided to the monitoring system 30 are, therefore, essentially raw signals.

The monitoring system 30 preferably also controls the providing of stimulation signals to the subject 46 via one or more stimulator systems 50. Various different types of stimulator systems 50 may be employed, including stimulator systems 50 for providing electrical, auditory, or visual stimulation. The stimulator systems 50 may be connected to the subject 46 via, for example, electrodes, for providing electrical stimulation to the subject, headphones, for providing auditory stimulation to the subject 46, or goggles including LEDs mounted thereon, for providing visual stimulation to the subject 46. The stimulator systems 50 preferably provide a signal back to the monitoring system 30 indicating the time at which a stimulation signal is provided to the subject . This signal allows the monitoring system 30 to synchronize the stimulation signals provided to the subject 46 with response signals received from the acquisition systems 48 for proper analysis and display of the relationship between the stimulus and response signals.

Other signals, such as video signals from a video camera 52, and sound signals from a microphone 54, may also be provided to the monitoring system 30. Conventional methods for digitizing the video and audio signals

provided by the video camera 52 and microphone 54 for use by the monitoring system 30 may be provided.

It should be understood that each of the hardware components illustrated in Fig. 1 may be implemented in a conventional manner, using conventional commercially available hardware devices. Also, the various hardware systems illustrated in Fig. 1 may be connected together in a conventional manner, using conventional cabling, connectors, etc. Alternatively, the various hardware systems illustrated in Fig. 1 may be connected together via a network bus topology, such as, for example, an IEEE 1394 high-speed serial bus topology. In the later case, the stimulus signals provided by the stimulator devices 50 and the response signals detected by the acquisition systems 48 may be time frame synchronized in the manner described in a co-pending U.S. Patent Application S.N. 09/320,613 entitled TIME FRAME SYNCHRONIZATION OF MEDICAL MONITORING SIGNALS.

The interface of signal acquisition systems 48 and stimulator systems 50 with a monitoring system 30 in accordance with the present invention is described in more detail with reference to the schematic block diagram of Fig. 2. The acquisition system 48 may include, for example, an acquisition board 56 into which the various signals from electrodes attached to the subject 46 are provided. The acquisition board 56 includes digital signal processor (DSP) firmware for converting the electrode signals into a format for transmission to the monitoring system computer 32 for analysis and display. The stimulator system 50 may include, for example, an electrical stimulation board 60, which receives signals from the monitoring system computer 32 controlling, for example, the magnitude, duration, and location of electrical simulation signals to be provided to the subject 46. The electrical stimulation board 60 is connected to the electrodes attached to the subject 46 via a switchbox 62, whereby the electrodes to which electrical stimulation signals are to be provided are selected. Auditory stimulation may be provided to the subject 46 via an auditory stimulation board 64. The auditory stimulation board 64 is connected to the monitoring system computer 32 via DSP firmware 66 which converts control signals from the computer 32 defining the

auditory stimulation to be provided to the subject 46 into the desired analog signals. (Similarly, a visual stimulation board, including DSP firmware, may be provided for visual stimulation.)

Low level host software 68 (kernel driver or library) running in the monitoring system computer 32 provides the interface to the acquisition 48 and stimulation 50 systems. The host software 68 provides the basic I/O interface between the DSP firmware 58 in the acquisition board 56, the electrical stimulation board 60, and the DSP firmware 66 in the auditory stimulation board 64 (and/or a visual stimulation board). The details of the host software 68 to be employed will depend upon the nature of the signals to be received from and provided to the acquisition 48 and stimulation 50 systems. The host software 68 provides the initial software interface between the acquisition 48 and stimulation 50 systems and the higher level software running in the monitoring system 30 for the analysis and display of the physiological signals received from the acquisition system 48, and control provided to the stimulation system 50. Although the host software 68 may require modification for different acquisition 48 and stimulation 50 systems which may be employed with the monitoring system 30 of the present invention, it is preferred that the higher level software running in the monitoring system 30 not need to be modified for use with different acquisition 48 and stimulation 50 systems. Thus, an acquisition abstraction layer (AAL) 70 is preferably implemented in the system computer 32 to provide an interface between the host software 68 and the higher level analysis, display, and control software running in the monitoring system computer 32. The AAL may be implemented in software in a conventional manner to allow for easy substitution of acquisition 48 and stimulation 50 systems, and corresponding low-level host software 68, without requiring modification of the higher level software running in the computer system 32. Details of implementing the AAL depend on the implementation of the host software 68 and the higher level display, analysis, and control software running in the monitoring system computer 32.

A medical signal monitoring system 30 in accordance with the present invention employs a simplified data pipeline concept which facilitates

flexible data storage, replay, analysis, display, and synchronization. An exemplary data pipeline 72 in accordance with the present invention will be described with reference to the schematic flow chart diagram of Fig. 3. Physiological signals from a subject are provided to the data pipeline 72 in essentially raw form. Thus, the data entering the data pipeline 72 may be, for example, the raw electrical signals detected by electrodes 74 attached to the subject 46. (It should be understood that basic processing such as signal amplification and some initial filtering may be provided by the acquisition system 48, as described previously, before the "raw" data signals are provided to the data pipeline 72.) The "raw" data entering the data pipeline 72 includes both physiological signals acquired by the acquisition system 48 as well as the timing signals provided by the stimulator system 50 indicating the providing of a stimulation signal to the subject 46.

The raw data entering the data pipeline 72 is provided initially along two paths, one for storage of the data, the other for display and analysis of the data. The raw data entering the data pipeline may be stored to disk 76. Simultaneously, the raw data entering the data pipeline is provided along the display and analysis path, where various processes are applied to the raw data signals. Such processes include, for example, montaging 78, wherein, for example, the signals provided from two electrodes 74 are combined in a desired manner to form a montaged pair 80. The montaged pair signal 80 may then be filtered with, e.g., a band pass filter for a desired frequency range of interest. In addition, variable band reject filtering may be applied to attentuate undesirable signals within a certain frequency range. The filtered signal 82 may be triggered 84 to be displayed in response to the appearance of a desired trigger condition. The signal may be averaged 86 before it is displayed. Spectral analysis of the signal may be performed, for example, by performing a Fast Fourier Transform (FFT) calculation 88 on the signal. Further calculations may be performed to determine and display the trend of the signal data 90. As will be described in more detail below, each of these processes applied to the signals to be displayed are operator selectable, and employ parameters which are user selectable by an operator employing a user interface.

At any point along the data processing pipeline 72, the processed signal may be displayed 92 on the system monitor 38. This will be described in more detail below. Also, at any point along the data pipeline 72, the processed signal may be saved to disk 44. For example, the averaged 94 and/or trend 96 signal may be saved to disk.

The data pipeline concept 72 illustrated in Fig. 3 is particularly useful in a medical signal monitoring system in accordance with the present invention. Raw data from the acquisition 48 and stimulator 50 systems may be either stored to disk 76 or passed along the data pipeline 72 for processing for analysis and display, or both simultaneously. The processing steps performed on the signal as it passes along the data pipeline 72 may be performed in any order, although montaging of data 78 to generate a montaged pair 80 is preferably the initial data processing step performed. Also, as discussed previously, a processed signal may be displayed and/or saved at any point along the data pipeline 72. The parameters employed for montaging, filtering, triggering, averaging, frequency analysis, and trend calculations are all preferably operator selectable. Also, the format in which the processed signal is displayed is preferably operator selectable. As will be described in more detail below, the present invention provides a user interface which facilitates the selection of each of these parameters and display formats.

The saving of raw signal data 76 to disk 44 is significant. This allows reanalysis and display of the data at any time using entirely different processing parameters. For example, upon initial processing, the signals provided by two electrodes may be montaged and processed to provide an EEG signal for analysis and display. At a later time, it may be desired to analyze an EMG signal between the first electrode and a third electrode located on the subject 46. Since the raw signal data from all of the electrodes is available on disk 44, the signals from the first and third electrodes may be montaged and processed to provide the desired EMG signal for analysis and display. Since incoming signal data is stored and/or processed as it is received, synchronization between the different signals generated for analysis and display therefrom is automatic.

A user interface for controlling the signal analysis and display features of a medical signal monitoring system 30 in accordance with the present invention preferably is implemented in software in the system computer 32 using a Windows-type operating system. A basic exemplary user interface and display screen 100, which may be displayed on the computer monitor 38 of a medical signal monitoring system 30 in accordance with the present invention, is illustrated in Fig. 4. The basic user interface and display screen 100 includes two basic components. Physiological signals to be displayed to an operator of the system 30 are presented in one or more windows 102 in the center part of the screen 100. As will be described in more detail below, each such window 102 in which physiologic signal data is displayed will be referred to as a panel. Different panels may be used to show different signals and/or different forms of signals. The signal display panel 102 includes the signal being displayed as well as appropriate labels for the signal.

In the margins of the screen 100 various buttons, pull-down menus, etc., are provided which form the user interface 104. The user interface 104 is implemented as a basic mouse/keyboard controlled Windows-like user interface. The various functions of the user interface 104 may be accessed, for example, by selecting features using the mouse 36. Additionally, keyboard shortcuts for certain functions are preferably operator definable. For example, each function key on the keyboard 34 may be assigned a user interface function. The functions assigned by the operator to each function key on the keyboard 34 are preferably displayed 106 on the user interface screen 100. A mouse-controlled menu 108 is preferably accessible by an operator to assign functions to each function key 106. A default name of the function may be assigned to the function key and displayed on the screen 106. Alternatively, the operator is preferably given the option of renaming 110 the function displayed in association with each key at 106. Thus, a function may be named with a label recognizable by a particular user. For example, a function assigned to a function key may be named in the native language of a user of the system. This allows common functions to be easily accessible by operators in various different languages, without requiring a complete reworking of the user interface into a different language. Note that the function keys on the keyboard 34

may be color-coded, with the corresponding display 106 of the functions assigned to each function key displayed on the screen 100 in the corresponding color.

Use of a medical signal monitoring system 30 in accordance with the present invention begins with a set-up procedure or mode wherein the operator of the system 30 defines the data of interest to be displayed on the system 30 and a format in which the information is to be displayed. In accordance with the present invention, physiological signals are displayed in windows called panels on the operator display 100. Preferably various different types of panels are available to an operator of the system 30, and multiple panels may be defined for a particular operator, patient, or monitoring session. A set of panels with associated user interface and stimulation parameters defined by an operator during the set-up phase or mode may be saved as a template.

After defining stimulus contexts, if any, as described in detail below, an operator of the system 30 continues the set-up process by selecting a panel type. The panel type defines the basic format in which the physiological signal data will be displayed. As illustrated in Fig. 5, a variety of different panel types which may be available to an operator of the system 30 include standard panels, stack panels, bar indicator panels, anatomic panels, and sweep line panels. Standard panels, sweep line panels, and stack panels are defined as wave panels, in which signal waveforms are displayed. In a standard panel waveform data scrolls from right to left, in a sweep line panel waveform data goes from left to right in an oscilloscope type fashion, in a stack panel waveforms are displayed in columns preferably scrolling from bottom to top. Each of these wave panel types will be described in more detail and illustrated as this detailed description proceeds.

In addition to wave panels, other panel types allowing the display of data in other formats may be provided. For example, an operator of the system 30 is preferably given the option of defining a bar indicator panel to display, for example, the instantaneous amplitude or area under a curve of a selected signal. An exemplary bar indicator panel display will be described and illustrated in more detail below. Another type of panel which is preferably made available to an operator of the system 30 is an anatomic or map panel. In an anatomic panel, for

example, the same parameters that can be displayed in the bar indicator panel can be displayed, for example, as a bar or circle, superimposed on a diagram of a human body in a color-coded fashion. A color scale, as is used in the bar indicator panel, may be employed. The diagram of a human body may be a bit map provided with the system 30 or by the operator. Using a pointing device, such as the mouse 36, an operator of the system 30 is preferably able to reposition the indicators on the bit map during run-time, and save the new layout during the set-up procedure.

Having selected a panel format in which physiological signal data is to be displayed, the system user interface allows an operator of the system 30 to define the signals which will be displayed in the panel. An exemplary user interface 120 for allowing an operator of the system 30 to define the signals to be displayed in a panel is illustrated in Fig. 6. For electrical physiological signals, for example, the signals to be displayed are defined in terms of electrodes positioned on the body of a subject 46. A set of electrodes are positioned on a subject's body, at various locations, to detect the electrical signals generated thereby. The electrodes may be labeled E1, E2, E3, etc. A user of the system 30 may re-label the electrodes 125, perhaps based on the position of the electrode on a subject's body. For example, ear, chin, elbow, biceps, triceps, and Cz, electrodes are labeled as such in the exemplary user interface 120. A signal to be displayed in a panel is defined by selecting a positive 122 and a negative 124 electrode signal from those available. For example, Fig. 6 shows the selection of a signal to be displayed which is defined by the ear electrode as the positive electrode signal source and the Cz electrode as the negative electrode signal source. The signal may be displayed as a montaged pair signal derived from the raw electrical signal provided to the data pipeline via the acquisition system 48 from the ear electrode and the raw electrode signal provided to the data pipeline via the acquisition system 48 from the Cz electrode.

Having identified the electrodes from which the signal to be displayed will be derived, an operator may then select the modality 126 of the signal to be displayed. In the exemplary embodiment shown in Fig. 6, an operator of the system is able to select between EEG, EMG, and EP modalities. Other or

different modalities may also be provided. The modality selected defines the filtering and other processing which will be applied to the electrode signals defined by the user before the signal is displayed.

Having selected the modality of the signal to be displayed, the operator of the system 30 may further define the type of wave form 128 to be displayed. The available types of wave forms may depend on the modality selected. Exemplary types of waveform signals to be displayed may include, for example, raw EEG, CSA, DSA, EEG-trend, free run EMG, triggered EMG, averaged triggered EMG, stimulated EMG, averaged stimulated EMG, and auditory, visual, and motor evoked potential (EP), etc.

The operator of the system 30 may preferably also set the display sensitivity value 130 for the signal to be displayed, and the time base (amount of seconds or milliseconds per panel) of the displayed signal 132.

A signal to be displayed, as just defined by the operator of the system 30, may be assigned a default label by the system. For example, the default label may be the pair of electrodes defining the signal. However, the user is preferably able to override the assigned label in order to assign custom labels 134.

Multiple signals to be displayed in a panel may be defined in the manner described. The signals to be displayed in a panel thus defined are listed in a portion 136 of the user interface window 120 wherein the signals to be displayed in the panel are defined. As illustrated by the example in Fig. 6, six signals to be displayed have been defined for a standard wave panel. The sixth signal thus defined is defined by a montaged pair to be derived from electrodes placed at the ear and Cz of a patient. The selected modality for the signal is EEG, and the type of signal to be displayed is a trend wave form. The display sensitivity has been set at a value of ten, with a time base for the display of one hour. Fig. 6 also illustrates, by example, five other signals which have been defined for display in this standard wave panel.

In accordance with the present invention, an operator of the medical signal monitoring system 30 is preferably able to control the filtering to be applied to the signals displayed in a panel (i.e., the montaged pair signal). An exemplary

user interface for providing such filter selection is illustrated at 140 in Fig. 7. Band pass filtering of the signal to be displayed may be defined by selecting desired low and high cutoff frequencies 142. Band pass filtering of the signal to be displayed may be implemented in software. An operator of the system 30 is preferably also able to select band-reject frequencies for the signal to be displayed. For example, a portion 144 of the user interface preferably allows an operator of the system to select one or more band-reject frequencies. Band-reject filtering of the signal to be displayed may be implemented in software, for example, as Butterworth band stop filters. Notch filtering of power line noise (e.g., at 50 or 60 Hertz) is preferably provided by the system 30. An operator of the system 30 is preferably given the option of turning on or off the notch filter by selecting a box 146 provided in the user interface 140.

As discussed above, a signal to be displayed by a medical signal monitoring system 30 in accordance with the present invention may be a triggered signal. As illustrated, for example, in Fig. 8, a portion of the user interface 150 preferably allows an operator of the system 30 to define the trigger for the triggered signal to be displayed. A triggered signal to be displayed may be triggered off of a stimulator signal, a trigger device, or a threshold level of the signal. (Further details on establishing a stimulator context for the signals displayed in a panel will be discussed below.) Thus, triggered signals to be displayed may be synchronized with a stimulator or with a level of the wave form (an operator definable level of triggering).

The user interface of a medical signal monitoring system 30 in accordance with the present invention preferably also provides a user interface 152 for defining an averaged signal to be displayed. An averaged signal is a special case of a triggered signal. In an averaged signal, the signal data is averaged over a period of time and the resulting averaged wave is displayed. As illustrated in Fig. 3, averaged data may be saved separately. The averaged data may be stored into a buffer. Two types of buffers may be provided, the sum of odd and even (normal average) and the difference of odd and even (noise estimate).

Data may be averaged starting at a trigger point, or, where the signal is triggered from a stimulus signal, with a pre-stimulus period. The maximum duration of the pre-stimulus period may be set equal to the duration of the post-stimulus period. Two types of averaging may be provided. In the first type of averaging, each new averaging period starts from scratch. Once an averaging period is completed, the results stay on the operator display screen until the operator restarts the averaging. A separate average pause/resume function may be provided to temporarily stop an averaging function. The second type of averaging is a moving average. A moving average is used to update data in a fast way. For example, the number of repetitions may be divided into a number of sub-averages (e.g., 10). Every completion of a new sub-average is added to the total after the first is subtracted. The total wave form is then displayed to an operator of the system 30. Averaging of a signal can be used in combination with electrical, visual, or auditory stimulation.

Artifact detection is provided to reject or accept sweeps contributing to the end result averaged signal to be displayed. An artifact state is defined if the signal exceeds a set sensitivity. Artifact detection is tied to individual input channels. If an artifact is detected in a channel, the trace is not added to the average or sub-average. The artifact part of a wave form may also be shown differently as a dotted line. When an averaged wave is displayed, the number of required periods, number of rejected periods, and type of average (normal or noise estimate) is preferably displayed along with the averaged wave form. Preferable a new average is scheduled every X minutes, where the value of X is under operator control.

As mentioned previously, a signal to be displayed in a wave panel may be displayed as a trend wave form. Preferably any type of monitored medical signal may be displayed as a trend, e.g., EEG, EP, or vital sign signals. For example, EEG trends may be based on the spectral parameters of a signal. Spectral bands are preferably operator definable and composed into any type of index. Preferably a portion 160 of the user interface, as illustrated, by example, in Fig. 9, allows operator selection of the spectral bands. For example, the user interface 160

may allow construction of co-efficients in the form of: (a1b1 + a2b2 + a3b3 + a4b4 + a5) / (c1b1 + c2b2 + c3b3 + c4b4 + c5) where the bands b1 to b4 may be designated as Delta, Theta, Alpha and Beta. The co-efficients ai and ci are also preferably operator definable. For evoked potential (EP) measured values, the trend plots can be for x-axis/y-axis displayed in various scales, such as linear/linear, linear/log, or linear/dB. For the dB scale, the plotted value y is calculated using: y = C log (value/reference value), with C = constant. The reference value is preferably also operator definable.

A portion 170 of the user interface, as illustrated, by example, in Fig. 10, preferably allows an operator of the system 30 to define other general characteristics of the signals to be displayed in a panel. Such user selectable features may include: whether or not a zero line is to be displayed in association with each trace, whether or not a wave to be displayed in a panel has a full panel or only part of the panel (total panel height/number of traces) allotted for the wave (clipping), whether or not a selected baseline is to be shown in the background of a wave form, the color of the waveform trace to be displayed, whether or not a sound representation of the signal is to be provided on the system speaker 42, and if so, what percentage of the displayed signal is included in the sound, and whether or not horizontal and vertical scales are to be provided, and if so, how they are to be indicated, e.g., as tick-marks or lines. An operator of the system 30 is preferably also able to define 178 the name of the panel in which signals are to be displayed. Other or different general features of this type may also be provided for formatting a signal to be displayed in a panel.

One or more panels may be defined in the manner described, and saved as a template. Different templates may be created for different operators, patients, monitoring sessions, etc. When data acquisition begins, one of the created templates is selected for displaying the data. Thus, once the set-up procedure has been performed, it need not be repeated unless another template is to be created or an existing template edited.

Having defined the physiological signals to be displayed, by defining one or more panels and the signals to be displayed therein, raw physiological

signals, e.g., signals from electrodes attached to a subject 46 and provided to the monitoring system 30 via acquisition hardware 48 may be provided to the monitoring system for display and analysis. As illustrated in Fig. 11, the user interface preferably provides an interface 180 to the operator of the system 30, allowing the operator of the system 30 to select the source of data which will be provided to the system 30. For monitoring the physiological signals provided by a subject 46, the acquisition system 48 (i.e., amplifiers) attached to the monitoring system 30 may be selected. Alternatively, simulated physiological signals, e.g., from one or more signal stimulators, may be selected as the data source. Simulated physiological signals may be employed, for example, to refine the display set-up of the wave forms to be displayed by an operator, or to test or calibrate the system 30. Beside "live" data, from either an acquisition system 48 or a simulator, an operator of the system may also review raw physiological signal data which has been stored on a disk 44.

As discussed previously, during the set-up mode an operator of a medical signal monitoring system 30 in accordance with the present invention defines the signals which are to be displayed and analyzed by the system 30. During an acquisition mode, physiological data of different modalities is displayed and/or recorded by the system. Preferably at least two acquisition modes are available to a user of the system. During a preview mode, raw physiological data is fed to the system (through the data pipeline 72) for analysis and display, but is not saved to disk. During record mode, raw physiological data is provided through the data pipeline 72 for analysis and display, and is simultaneously saved to disk 44 for later review.

An exemplary operator screen 100 displayed during acquisition mode is shown in Fig. 12. The exemplary screen display shown in Fig. 12 illustrates by example various different panels which have been defined by an operator of the system during the set-up mode to display various signals. The exemplary screen display of Fig. 12 shows exemplary wave panels 190, including a stack panel 192. An exemplary bar indicator panel 194 is also shown. As described previously, the bar indicator panel 194 is used to display parameters associated with a waveform

signal. The update rate of the bar indicator panel depends on the type of data being displayed. The data displayed in the bar indicator panel 194 is displayed as a bar with color indicators which may be both size and color coded. For example, a default color scheme for the bar indicator panel 194 may be a heat scale: blue, green, red, yellow, and white. However, an operator of the system 30 is preferably able to define different color scales. The bar indicator panel 194 may preferably be resized, in which case, the indicators in the panel should be resized correspondingly. However, a meaningful lower limit for the indicator size should be enforced. When the bar indicator panel 194 is sized to take up the full screen, the bars displayed therein are preferably readable from a distance (e.g., 3 meters on a 14 inch screen). Thus, the bar indicator panel 194 may prove particularly useful in operating room situations or the like.

In accordance with the present invention, the user interface preferably provides for interaction with the various panels defined and the various signals displayed thereon. For example, stack panels 192, and panels showing trend data, allow inspection of the long term environment/context of a measured signal. An operator of the system is preferably able to zoom in and out of such data to review the context of the underlying signal. In a view mode, an operator of the system may employ the user interface pointing device 36 to grab a selected portion of a signal (in a stack panel 192 or trend display) and drag it into a wave panel, to display the corresponding data in a wave panel in a still fashion (the data doesn't scroll). The user interface preferably allows the user to drag a cursor from the stack or trend into an existing panel. This will create a duplicate panel of the type the cursor was dragged into. Signal data corresponding to the cursor position will be displayed accordingly. Of course, such a function may only be available for recorded data, i.e., in preview mode, where data is not recorded, this function cannot be performed.

The user interface of a medical monitoring system 30 in accordance with the present invention preferably also provides for the making of remarks, annotations, or comments on the signals displayed in a panel. For example, in a standard wave panel, the user interface preferably provides for the placing of

annotations in the signal display area. In a stack panel, a separate column may be made available for textural remarks, annotations, or comments. An exemplary user interface 200 for providing a comment to a stack panel 201 is illustrated in Fig. 13. As illustrated, such comments may be time stamped and/or attached to a specific wave form. Any comments thus made may be compiled in a list that serves as a basis for searching. Such annotations can be made as a free-text or as a predefined statement. An annotation can be made as a time stamped text or connected to a wave form. The ability to make an annotation synchronized with a video period may also be provided.

The user interface of a medical monitoring system 30 in accordance with the present invention preferably also provides a tool which allows the operator of the system 30 to measure signal values. For example, a triggered wave form 208 is displayed in a wave panel 210 in Fig. 14. To measure values of the wave form 208 on the fly, two cursors 212 and 214 are provided. One cursor may, for example be in the shape of a "+", the other in the shape of an "X". Other shapes for the cursors 212 and 214 may also be made available, such as bars 216. The two cursors 212 and 214 are placed at desired positions on the wave form 208. A status bar 218 of the panel 210 displays variables associated with the cursor position, for example, the amplitude and latencies of both cursors, and the difference of the amplitude and latency values. Thus, the cursors 212 and 214 provide a ruler that allows a quick measurement of a wave form 208.

Another user interface method which is preferably provided to measure values of a wave form employs markers. The use of markers in accordance with the present invention is described, for example, with reference to Fig. 15, where a wave form 220 displayed in a wave panel 222 is to be measured. The use of markers to measure a wave form may be performed on either triggered or averaged data. An operator may preferably turn on a plurality, e.g., up to 7, markers per wave form. Markers can detect and mark peaks or valleys. The first time a wave is measured, markers 224 are set by an operator of the system 30, e.g., using the mouse 36. When a marker 224 is placed, the system 30 automatically sets the marker until the operator redefines the marker by overriding the system

position. When a marker is set, the software recognizes if it is a peak or trough (maximum or a minimum). The system looks for the same peak or trough within X% of the latency of the defined one in all subsequent wave forms. The value of the percentage can be defined by an operator, e.g., via user interface window 226, as illustrated, for example, in Fig. 15. The label, latency, and/or amplitude (absolute and relative) of the detected extreme values in the wave form 220 can thus be displayed 228 using the markers 224. As illustrated in Fig. 15, displayed relative amplitude or latency 228 is relative to the following marker in sequence. The values of marked waves may also be stored in a measurement table, as they come in with a time stamp. Those values may be displayed or exported to a report generator or spreadsheet for further analysis.

A user interface for a medical signal monitoring system 30 in accordance with the present invention preferably provides a look-back mode, enabling an operator of the system 30 to examine more carefully a portion of a wave form passing through a wave panel. An exemplary look-back window 230 is illustrated in Fig. 16. The look-back window shows a segment 231 of a previously recorded (and displayed) wave form. For example, up to ten seconds of the wave form 231 may be shown in the look-back window. The wave form 231 shown in the look-back window 230 is frozen in time. A look-back control panel 232 is provided, whereby an operator of the system can scroll backward or forward in time, thereby changing the portion of the wave form 231 shown in the look-back window 230, to find and observe in more detail a particular portion of the wave form of interest. When the look-back mode is terminated, the wave form 231 is released from its frozen state, and is resynchronized with active acquisition, i.e., the wave form displayed jumps forward to real-time.

As mentioned previously, a medical signal monitoring system 30 in accordance with the present invention may preferably be used to control a stimulator system 50 for providing stimulation signals to a subject 46. The user interface of a monitoring system 30 in accordance with the present invention preferably provides a mechanism for defining the stimulation to be applied to the subject 46, as well as for coordinating the display of response signals received by

the system 30 from the subject 46 in response to the stimulation provided. For example, as discussed previously, signals to be displayed by the monitoring system 30 may be triggered based upon stimulus signals. Similarly, an averaged signal to be displayed may be averaged based on the occurrence of a stimulus signal.

Preferably, the user interface allows a set of stimulus settings to be established for each panel of signals to be displayed. The stimulus settings for a signal panel is defined as a stimulus context. Different panels may have different stimulus contexts. One set of stimulus settings may be defined as the stimulus context for one panel, with another set of stimulus settings established as the stimulus context for another panel. The stimulus that is actually provided to a subject is determined by selecting one of the panels, and, therefore, the stimulus context of that panel, as the active panel. The stimulation to be provided to a subject may be changed easily during acquisition, by simply selecting a different panel, and, therefore, a different stimulus context, as the active panel. A more detailed discussion of the concept of establishing a stimulus context will now be provided.

An exemplary method of stimulus generation will be described with reference to the schematic block diagram of Fig. 17. As described previously, a medical signal monitoring system 30 in accordance with the present invention may be used to drive various stimulator devices 250. Such stimulator devices may include, one or more electrical (current) stimulators, an auditory stimulator, and/or a visual stimulator. The various stimulators 250 are driven by one or more rate generators 252 implemented in the monitoring system computer 32. Preferably a plurality of rate generators are available, with each rate generator connected via switching mechanisms to one or more of the available stimulator devices 250. The different rate generators may each be synchronized with averaged or triggered signal acquisition, in order to allow pseudo simultaneous data acquisition. In the example of Fig. 17, two triggers or rate generators are provided to be connected to various stimulators 250. Both generators 252 can be connected any of the stimulators 250 using conventional software controled switches. The electrical

stimulators 250 may be multiplexed, via stimulus switching devices 254, in the stimulator system 50.

An example of a stimulus setting, based on the diagram of stimulus generation presented in Fig. 17, which may be established using the user interface of the present invention, is illustrated in Fig. 18. Two rate generators (triggers) 260 and 262 are employed. Three traces or signals to be displayed are defined by an operator of the system 30 employing the user interface in the manner described above. One of the signals to be displayed, signal Z 268, is defined as a free-run signal. Thus, the display of signal Z in a panel is not tied to any stimulation signal. The other two traces, signal X 264 and signal Y 266, are synchronized to different triggers 260 and 262, respectively. The first rate generator (trigger 1) 260 is, in turn, coupled to provide trigger signals to an auditory stimulator 270 and an electrical current stimulator 272. Thus, signal X to be displayed is synchronized to auditory and electrical current stimulation signals. The second rate generator (trigger 2) 262 is connected to control a second current stimulator 274. Thus, the display of signal Y is synchronized to stimulus signals provided to a subject 46 via electrical current stimulator 274. The auditory stimulator device 270 generates clicks, the electrical current stimulator devices 270 and 274 generate current pulses, and, if available, a visual stimulator would provide light flashes, at the occurrence of triggers provided by the rate generator trigger devices 260 and 262. A measured signal is synchronized with the stimuli. Thus, in the example of Fig. 18, displayed signal X is synchronized with trigger 1 and displayed signal Y with trigger 2. This results in a panel wherein each signal trace X and Y is the result of a different stimulator. However, they are recorded in the same time interval. The multiplexing of the stimulators may be accomplished by switching periodically in a round-robin fashion.

Fig. 18 illustrates a stimulus context for one panel. Other stimulus contexts may be defined for other panels. The context of the stimulation provided to a subject is changed by selecting different panels in the user interface.

An exemplary user interface for establishing a stimulus context is illustrated at 280 in Fig. 19. The stimulator set-up user interface 280 allows an

operator of the system 30 to define the rate, duration of stimulus, etc., of the stimulators, as well as to define the stimulators that are on. It also allows the operator to specify the pattern in which the electrical stimulators, visual stimulator and auditory stimulator are activated. An operator defines the pattern itself in the context set-up. In the panel set-up described previously, the operator selects a context, from a list of thus defined contexts, for a panel, if desired. Because the context is global for a panel, switching from one context to another is done by switching the active panel. Each signal in the panel can be synchronized with a unique stimulator channel. The stimulator set-up user interface 280 is used to define a stimulator context by entering a name for the context, and determining how to control the stimuli. Control may be either internal or external. In the case of internal control, the stimuli are continuous or gated. Either one or both of the two available rate generators, in this case, are selected to be attached to the stimulators, which may be, as discussed above, electrical, auditory, or visual. Rates and the delay between the two generators can be set. Additional user interface windows allow other settings to be established by the operator, such as, for example, duration, type, maximum intensity, intensity, stimulus site, mode, train rate, etc., for electrical stimulators, duration, polarity, transducer, and decibels, for each of left and right auditory stimulators, and mode, train rate, and count for visual stimulators, etc. Once a stimulator context has been established, it may be selected during panel set-up, to thereby assign the particular stimulator context to a particular panel of signals to be displayed.

An exemplary screen display provided by a medical signal monitoring system 30 in accordance with the present invention is illustrated at 290 in Fig. 20. Exemplary screen display 290 includes various panels as defined during set-up mode, displaying various different types of data. These panels include a trend panel 292, as well as panels 294 showing evoked potential wave forms in response to stimulus signals, wherein the stimulator context is defined for each panel in the manner described previously. The screen display 290 of Fig. 20 also shows, for example, a video window 296 in which, for example, a video image of a subject 46 taken by the video camera 52 may be displayed. Also shown are user

interfaces 298, 299, and 300 for controlling, in real-time, various parameters of auditory, visual, and electrical stimulation, respectively, being applied to the subject 46.

It should be understood that many of the signal processing functions mentioned herein may be performed in a conventional manner. A medical signal monitoring system 30 in accordance with the present invention may be coupled to other software programs, such as patient databases, report generators (word processors), and/or spreadsheets, to exchange data therebetween in a conventional manner.

It is understood that the present invention is not limited to the particular embodiments, examples, and applications illustrated and described herein, but embraces all such modified forms thereof as, as come within the scope of the following claims.

CLAIMS

What is claimed is:

1. A method for displaying physiological signals of a subject, comprising the steps of:

(a) receiving a plurality of raw wide band physiological signals from a plurality of portions of a subject's body;

(b) selecting at least one first pair of the plurality of raw wide band physiological signals;

(c) selecting a first modality of interest;

(d) combining and filtering the first pair of raw wide band physiological signals for the modality of interest to define a first physiological signal to be displayed; and

(e) displaying the first physiological signal to be displayed.

2. The method of Claim 1 wherein the step of receiving a plurality of raw wide band physiological signals includes the step of attaching a plurality of electrodes to the plurality of portions of the subject's body.

3. The method of Claim 1 wherein the step of receiving a plurality of raw wide band physiological signals includes the step of receiving a plurality of electrical physiological signals wherein a frequency range of each electrical physiological signal is wide enough to include EEG, EMG and EP frequency bands.

4 The method of Claim 3 wherein the step of selecting a first modality of interest includes the step of selecting a frequency range corresponding to a frequency band selected from the group of frequency bands consisting of EEG, EMG and EP frequency bands.

5. The method of Claim 1 wherein the step of combining the first pair of raw wide band physiological signals includes the step of montaging the first pair of raw wide band physiological signals.

6. The method of Claim 1 comprising additionally the step of defining a format in which the first physiological signal to be displayed is displayed.

7. The method of Claim 6 wherein the step of defining a format in which the first physiological signal to be displayed is displayed includes the step of selecting a panel in which the first physiological signal to be displayed is to be displayed from a plurality of panel types, wherein a different format for displaying a physiological signal is assigned to each panel type.

8. The method of Claim 1 comprising additionally the steps of:

(a) selecting a second pair of the plurality of raw wide band physiological signals;

(b) selecting a second modality of interest;

(c) combining and filtering the second pair of raw wide band physiological signals for the second modality of interest to define a second physiological signal to be displayed; and

(d) displaying the second physiological signal to be displayed.

9. The method of Claim 8 wherein the second pair of raw wide band physiological signals includes at least one raw wide band physiological signal included in the first pair of raw wide band physiological signals.

10. The method of Claim 9 wherein the second modality of interest is different from the first modality of interest.

11. The method of Claim 8 wherein the second physiological signal to be displayed is displayed simultaneously with the first physiological signal to be displayed.

12. The method of Claim 1 comprising additionally the step of saving the plurality of raw wide band physiological signals.

13. The method of Claim 12 comprising additionally the steps of:

(a) selecting at least one pair of the saved plurality of raw wide band physiological signals;

(b) selecting a third modality of interest;

(c) combining and filtering the selected pair of saved raw wide band physiological signals for the third modality of interest to define a third physiological signal to be displayed; and

(d) displaying the third physiological signal to be displayed.

14. The method of Claim 13 wherein the selected pair of saved raw wide band physiological signals includes at least one raw wide band physiological signal corresponding to at least one of the raw wide band physiological signals included in the first pair of raw wide band physiological signals.

15. The method of Claim 13 wherein the third modality of interest is different from the first modality of interest.

16. A medical monitoring system for displaying physiological signals of a subject, comprising:

(a) means for receiving a plurality of raw wide band physiological signals from a plurality of portions of a subject's body;

(b) a user interface for selecting pairs of the plurality of raw wide band physiological signals, wherein any one of the raw wide band physiological signals may be included in more than one pair, and for selecting a modality for each selected pair of raw wide band physiological signals;

(c) means for combining and filtering the signals in each selected pair of raw wide band physiological signals for the corresponding modality to define physiological signals to be displayed; and

(d) means for displaying the physiological signals to be displayed.

17. The medical monitoring system of Claim 16 wherein the means for receiving a plurality of raw wide band physiological signals includes a physiological signal acquisition system including a plurality of electrodes attached to the plurality of portions of the subject's body.

18. The medical monitoring system of Claim 17 wherein the physiological signal acquisition system provides a plurality of electrical physiological signals wherein a frequency range of each electrical physiological signal is wide enough to include EEG, EMG and EP frequency bands.

19. The medical monitoring system of Claim 16 wherein the user interface for selecting a modality for each selected pair of raw wide band physiological signals includes means for selecting a frequency range corresponding to a frequency band selected from the group of frequency bands consisting of EEG, EMG and EP frequency bands for each selected pair of raw wide band physiological signals.

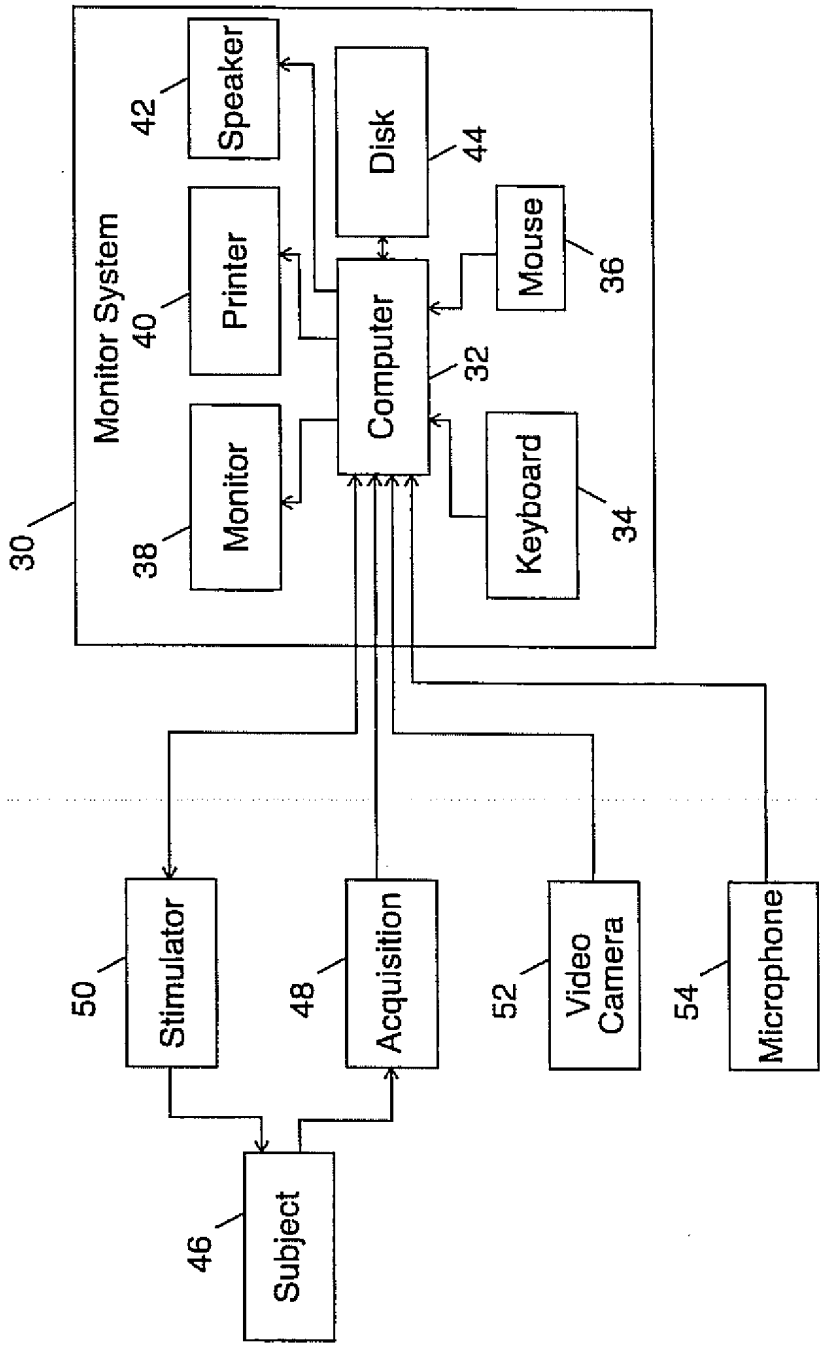
20. The medical monitoring system of Claim 16 wherein the means for combining the signals in each selected pair of raw wide band physiological signals includes means for montaging the signals in each selected pair of raw wide band physiological signals.

21. The medical monitoring system of Claim 16 comprising additionally means for defining formats in which the physiological signals to be displayed are displayed.

22. The medical monitoring system of Claim 21 wherein the means for defining formats in which the physiological signals to be displayed are displayed includes means for selecting panels in which the physiological signals to be displayed are to be displayed from a plurality of panel types, wherein a different format for displaying a physiological signal is assigned to each panel type.

23. The medical monitoring system of Claim 16 comprising additionally means for saving the plurality of raw wide band physiological signals.

24. The medical monitoring system of Claim 23, wherein the user interface includes means for selecting pairs of the saved plurality of raw wide band physiological signals, wherein any one of the saved plurality of raw wide band physiological signals may be included in more than one pair, and for selecting a modality for each selected pair of saved raw wide band physiological signals; wherein the means for combing and filtering includes means for combining and filtering the selected pairs of saved raw wide band physiological signals for the corresponding modality to define physiological signals to be displayed; and wherein the means for displaying includes means for displaying the physiological signals to be displayed.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Speaker
42
Disk
44
Printer
40
Computer
32
Mouse
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Monitor
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Keyboard
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Stimulator
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Acquisition
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Video Camera
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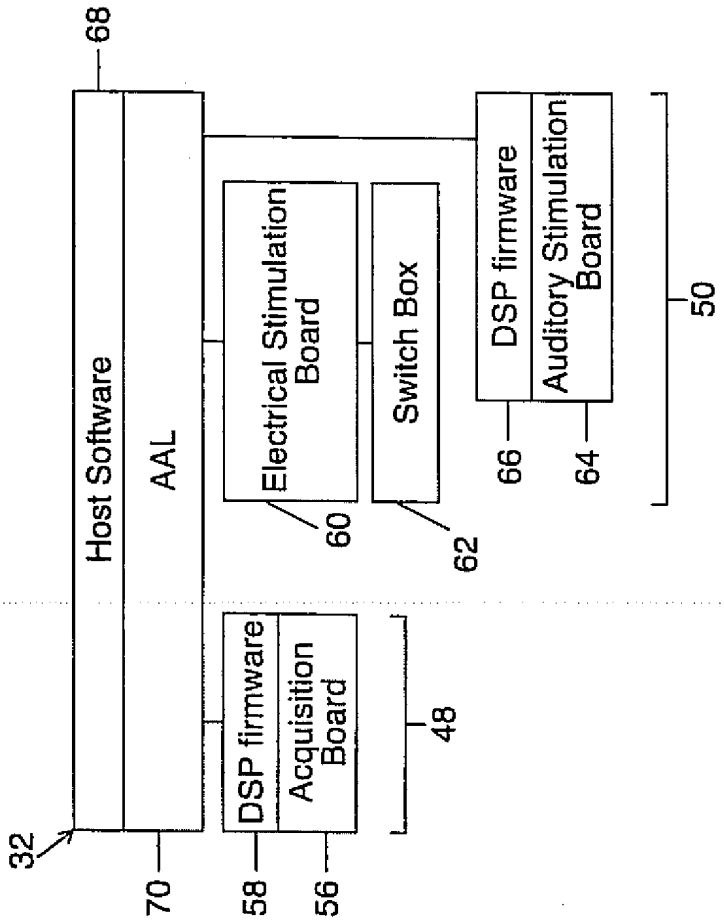
Microphone
54
Subject
46

FIG. 1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Host Software
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Electrical Stimulation Board
Switch Box
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62
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32
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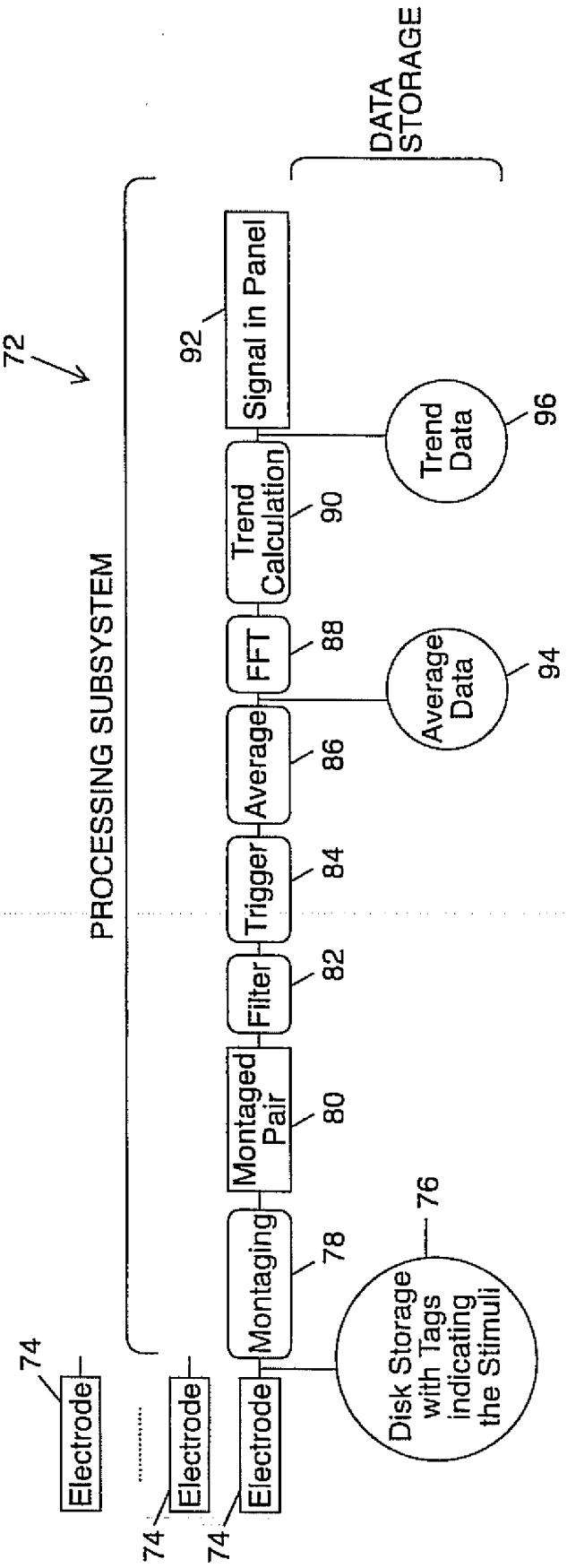
DSP firmware
Acquisition Board
48

FIG. 2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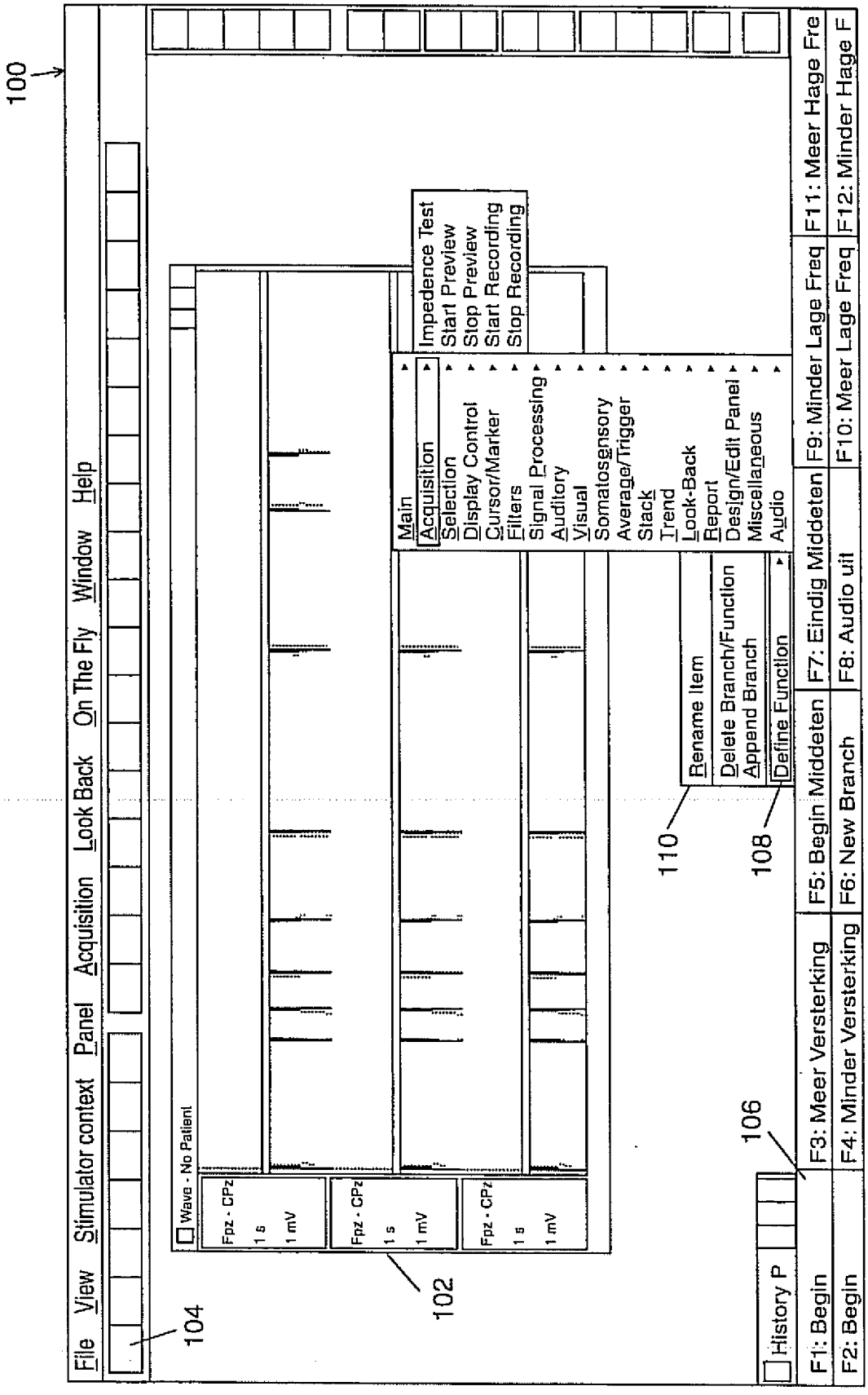
PROCESSING SUBSYSTEM
DATA STORAGE
74
Electrode
Electrode
Electrode
Montaging
78
Montaged Pair
80
Filter
82
Trigger
84
Average
86
FFT
88
Trend Calculation
90
92
Signal in Panel
Disk Storage with Tags indicating the Stimuli
76
Average Data
94
Trend Data
96

FIG. 3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Wave - No Patient
Fpz - CPz
1 s
1 mV
102
104
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Acquisition
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Display Control
Cursor/Marker
Filters
Signal Processing
Auditory
Visual
Somatosensory
Average/Trigger
Stack
Trend
Look-Back
Report
Design/Edit Panel
Miscellaneous
Audio
Impedence Test
Start Preview
Stop Preview
Start Recording
Stop Recording
Rename Item
Delete Branch/Function
Append Branch
Define Function
110
108
106
History P
F1: Begin
F2: Begin
F3: Meer Versterking
F4: Minder Versterking
F5: Begin Middeten
F6: New Branch
F7: Eindig Middeten
F8: Audio uit
F9: Minder Lage Freq
F10: Meer Lage Freq
F11: Meer Hage Fre
F12: Minder Hage F

FIG. 4

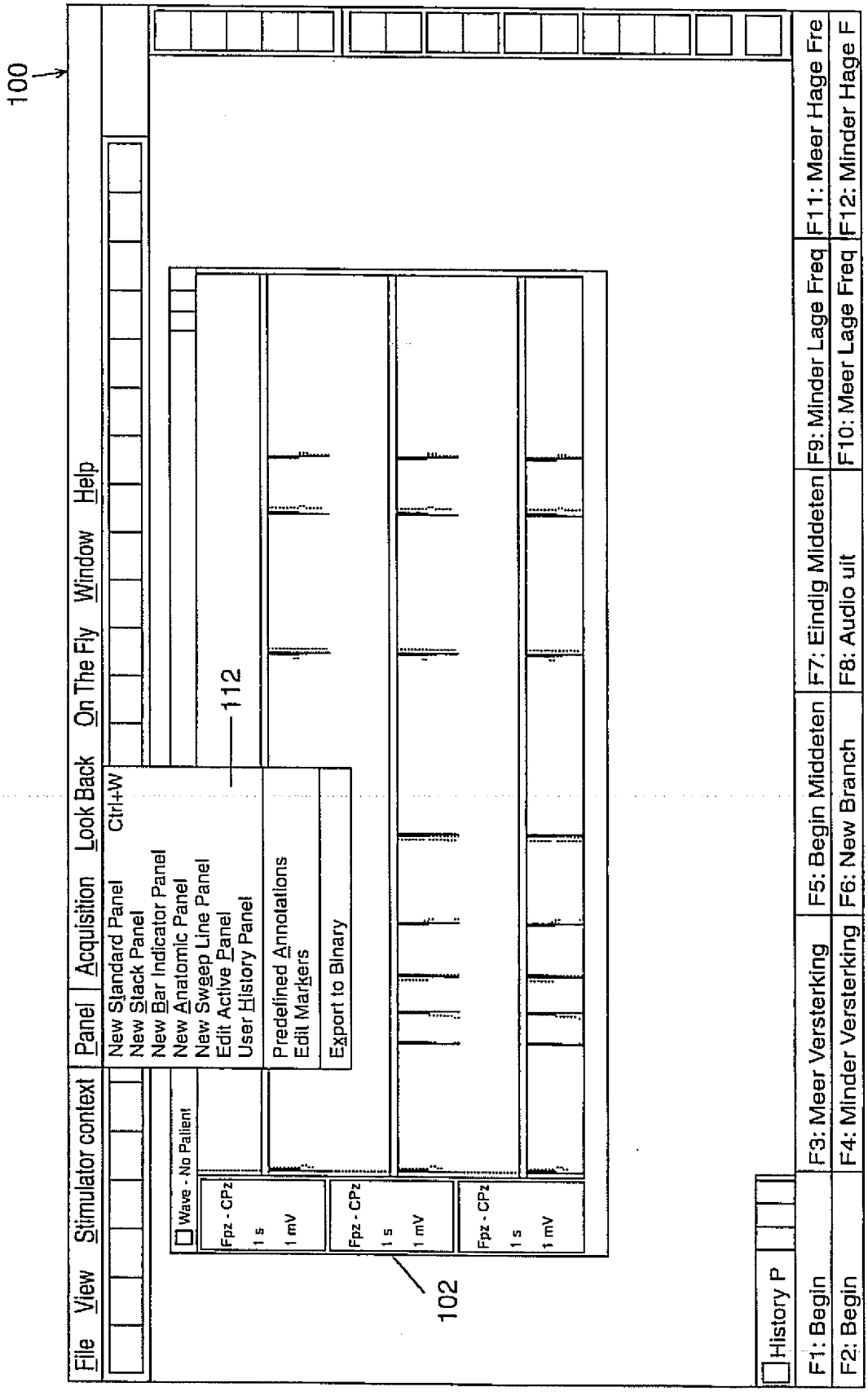
100
File View Stimulator context Panel Acquisition Look Back On The Fly Window Help
New Standard Panel Ctrl+W
New Stack Panel
New Bar Indicator Panel
New Anatomic Panel
New Sweep Line Panel
Edit Active Panel
User History Panel
Predefined Annotations
Edit Markers
Export to Binary
112
Wave - No Patient
Fpz - CPz
1 s
1 mV
102
History P
F1: Begin
F2: Begin
F3: Meer Versterking
F4: Minder Versterking
F5: Begin Middeten
F6: New Branch
F7: Eindig Middeten
F8: Audio uit
F9: Minder Lage Freq
F10: Meer Lage Freq
F11: Meer Hage Fre
F12: Minder Hage F

FIG. 5

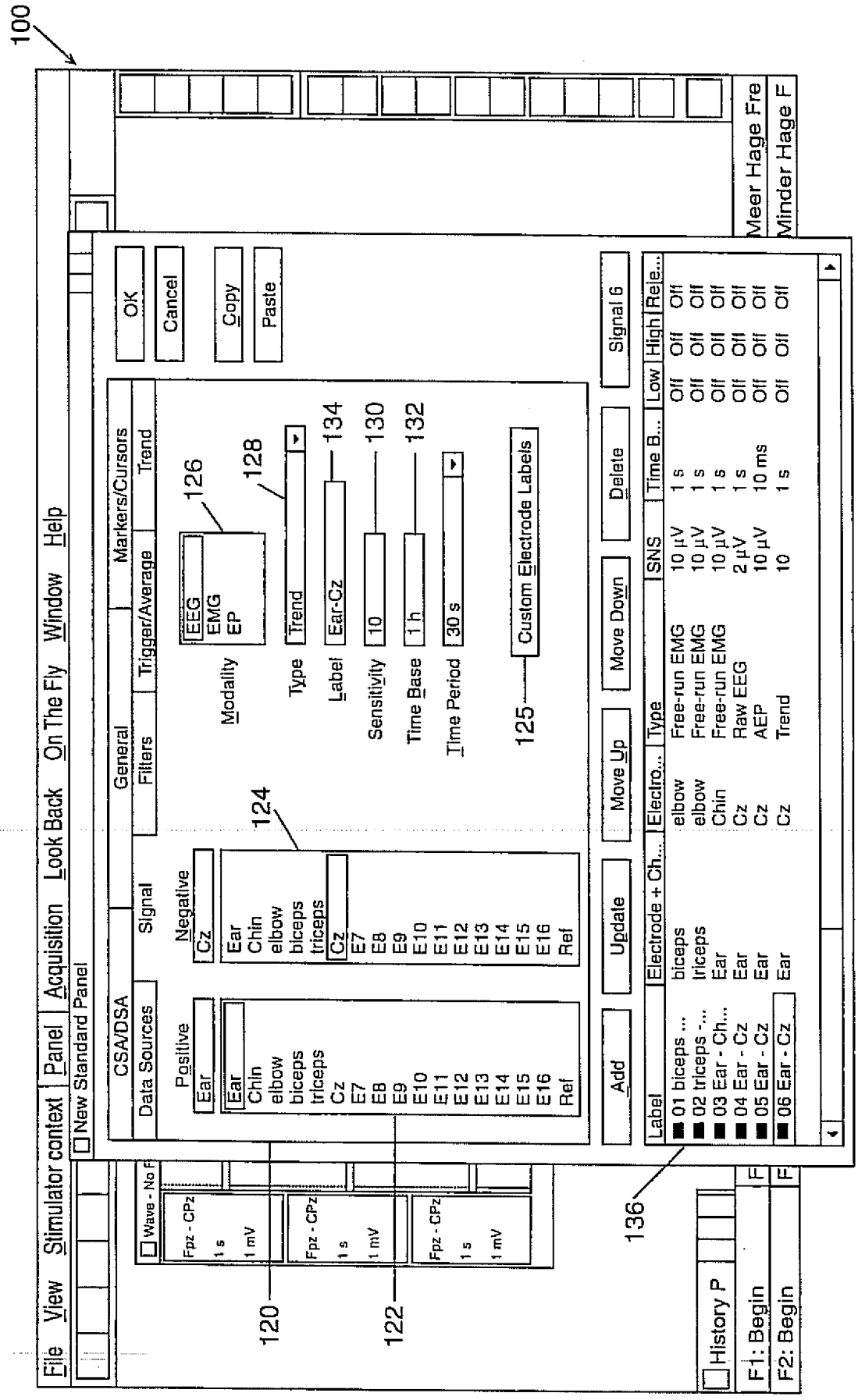
100
File View Stimulator context Panel Acquisition Look Back On The Fly Window Help
New Standard Panel
CSA/DSA
Data Sources
Signal
General
Filters
Trigger/Average
Markers/Cursors
Trend
OK
Cancel
Copy
Paste
Positive
Negative
Ear
Chin
elbow
biceps
triceps
Cz
E7
E8
E9
E10
E11
E12
E13
E14
E15
E16
Ref
124
Modality
EEG
EMG
EP
126
128
Type
Trend
Label
Ear-Cz
134
Sensitivity
10
130
Time Base
1 h
132
Time Period
30 s
125
Custom Electrode Labels
Add
Update
Move Up
Move Down
Delete
Signal 6
Label
Electrode + Ch...
Electro...
Type
SNS
Time B...
Low
High
Rele...
01 biceps ...
biceps
elbow
Free-run EMG
10 µV
1 s
Off
Off
Off
02 triceps -...
triceps
elbow
Free-run EMG
10 µV
1 s
Off
Off
Off
03 Ear - Ch...
Ear
Chin
Free-run EMG
10 µV
1 s
Off
Off
Off
04 Ear - Cz
Ear
Cz
Raw EEG
2 µV
1 s
Off
Off
Off
05 Ear - Cz
Ear
Cz
AEP
10 µV
10 ms
Off
Off
Off
06 Ear - Cz
Ear
Cz
Trend
10
1 s
Off
Off
Off
Wave - No F
Fpz - CPz
1 s
1 mV
120
122
136
History P
F1: Begin
F2: Begin
Meer Hage Fre
Minder Hage F

FIG. 6

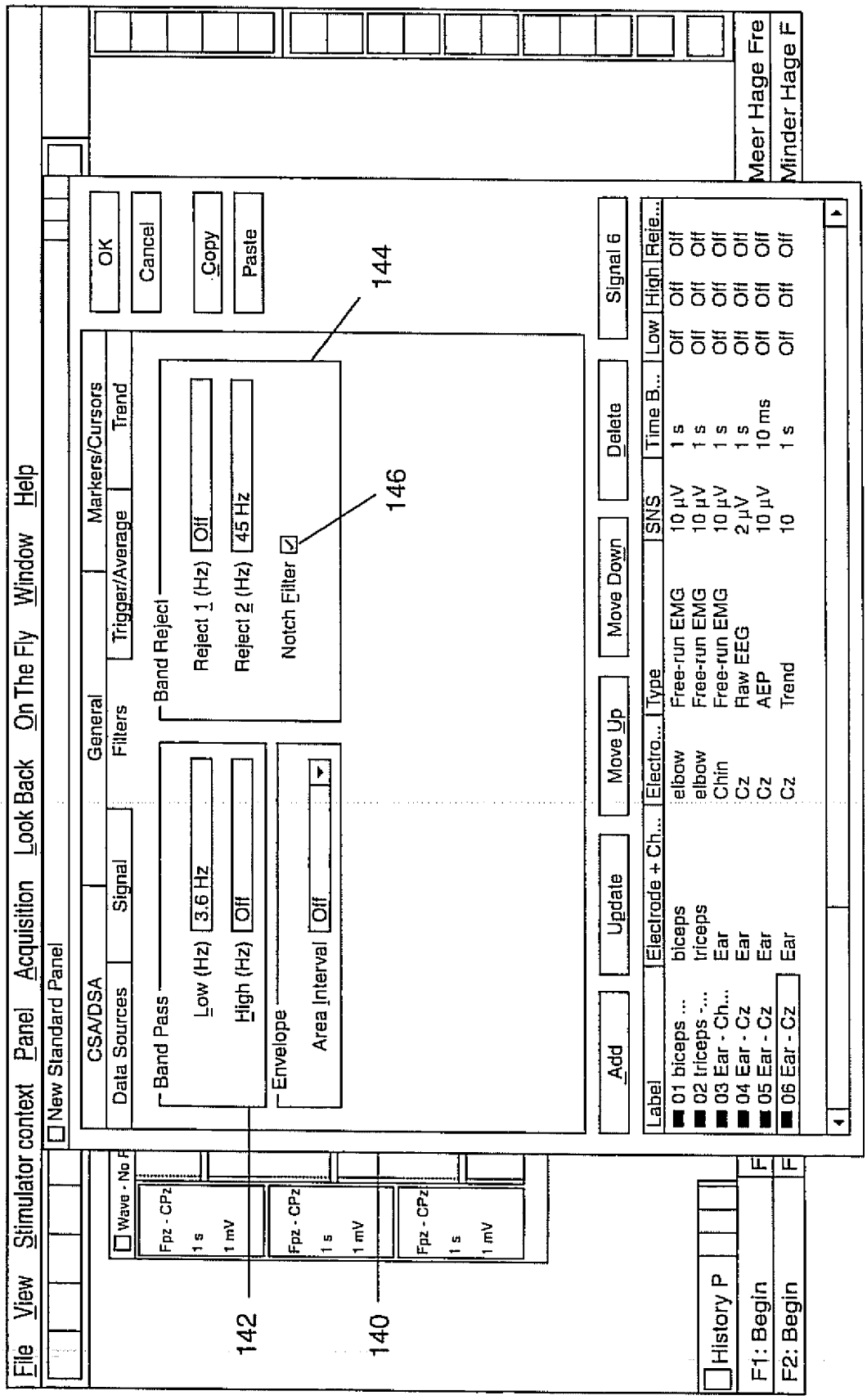
File View Stimulator context Panel Acquisition Look Back On The Fly Window Help
New Standard Panel
CSA/DSA
General
Markers/Cursors
Data Sources
Signal
Filters
Trigger/Average
Trend
Band Pass
Low (Hz) 3.6 Hz
High (Hz) Off
Envelope
Area Interval Off
Band Reject
Reject 1 (Hz) Off
Reject 2 (Hz) 45 Hz
Notch Filter
OK
Cancel
Copy
Paste
Add
Update
Move Up
Move Down
Delete
Signal 6
Label
Electrode + Ch...
Electro...
Type
SNS
Time B...
Low
High
Reje...
01 biceps ...
biceps
elbow
Free-run EMG
10 µV
1 s
Off
Off
Off
02 triceps -...
triceps
elbow
Free-run EMG
10 µV
1 s
Off
Off
Off
03 Ear - Ch...
Ear
Chin
Free-run EMG
10 µV
1 s
Off
Off
Off
04 Ear - Cz
Ear
Cz
Raw EEG
2 µV
1 s
Off
Off
Off
05 Ear - Cz
Ear
Cz
AEP
10 µV
10 ms
Off
Off
Off
06 Ear - Cz
Ear
Cz
Trend
10
1 s
Off
Off
Off
Wave - No F
Fpz - CPz
1 s
1 mV
History P
F1: Begin
F2: Begin
Meer Hage Fre
Minder Hage F
142
140
144
146

FIG. 7

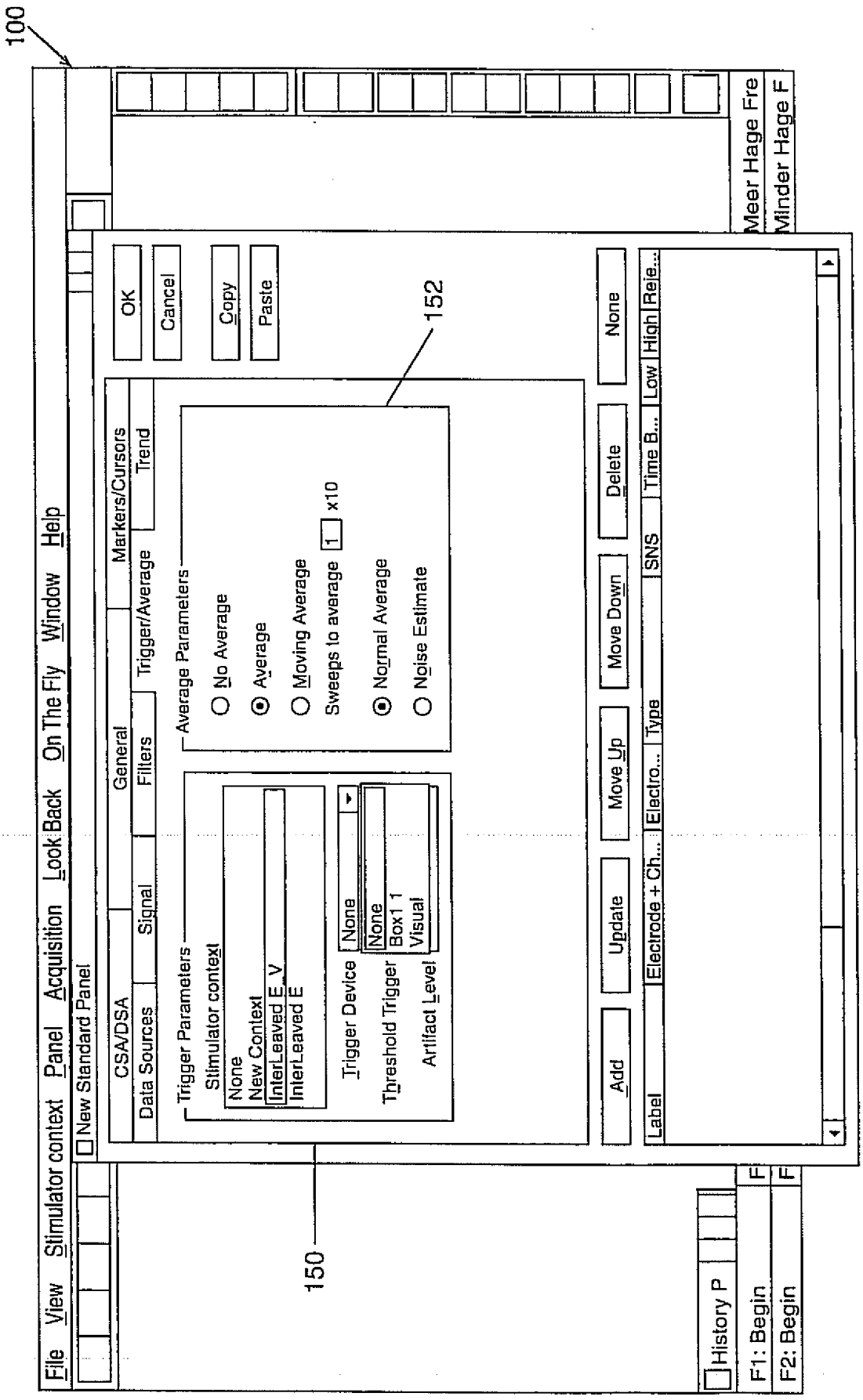
100
File View Stimulator context Panel Acquisition Look Back On The Fly Window Help
New Standard Panel
CSA/DSA
Data Sources
Signal
Filters
General
Trigger/Average
Markers/Cursors
Trend
Trigger Parameters
Stimulator context
None
New Context
InterLeaved E_V
InterLeaved E
Trigger Device
Threshold Trigger
Artifact Level
None
None
Box1 1
Visual
Average Parameters
No Average
Average
Moving Average
Sweeps to average 1 x10
Normal Average
Noise Estimate
OK
Cancel
Copy
Paste
152
150
Add
Update
Move Up
Move Down
Delete
None
Label
Electrode + Ch...
Electro...
Type
SNS
Time B...
Low
High
Reje...
Meer Hage Fre
Minder Hage F
History P
F1: Begin
F2: Begin

FIG. 8

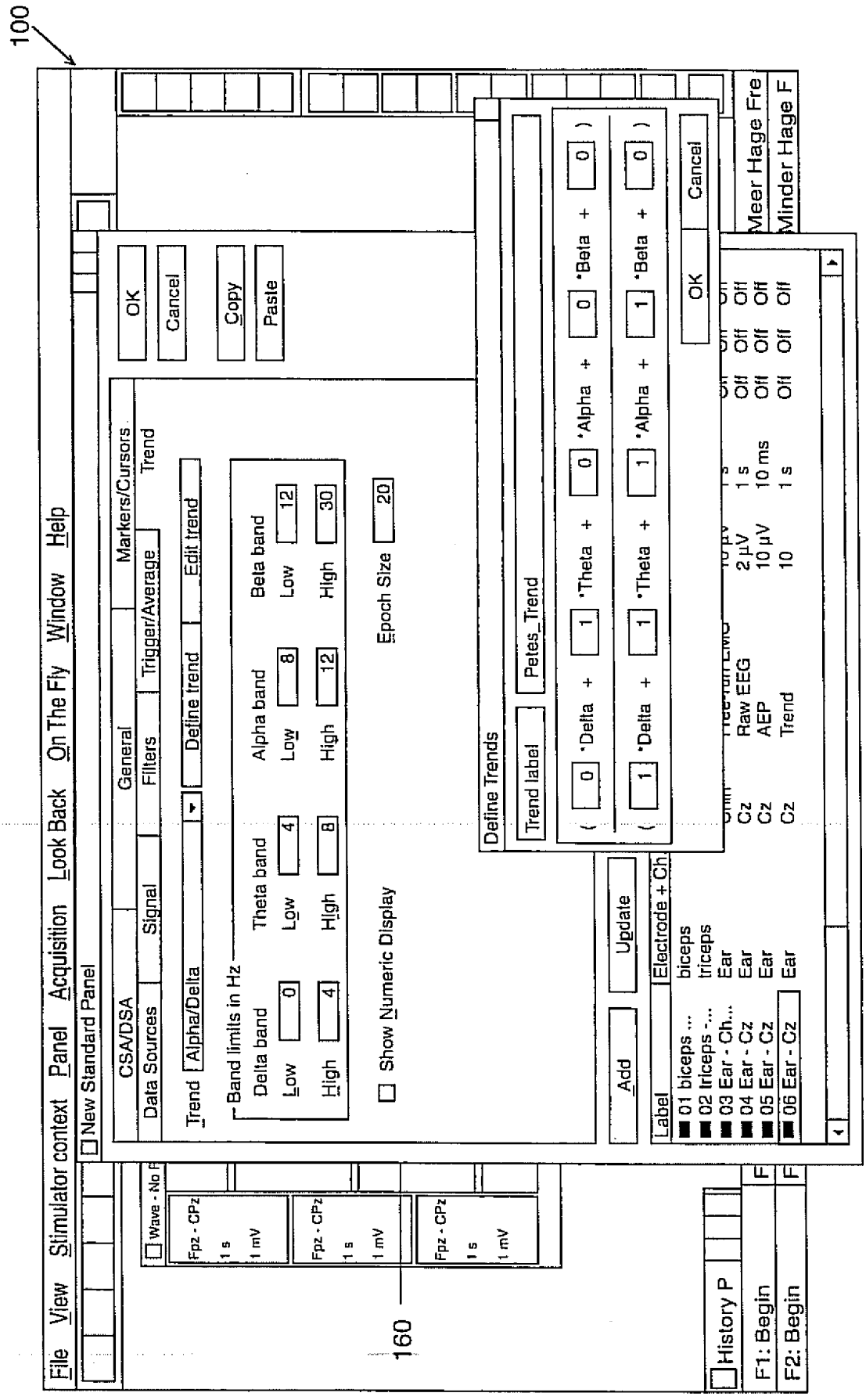
100
160
File View Stimulator context Panel Acquisition Look Back On The Fly Window Help
New Standard Panel
CSA/DSA
General
Markers/Cursors
Data Sources
Signal
Filters
Trigger/Average
Trend
Trend Alpha/Delta
Define trend
Edit trend
Band limits in Hz
Delta band
Low 0
High 4
Theta band
Low 4
High 8
Alpha band
Low 8
High 12
Beta band
Low 12
High 30
Epoch Size 20
Show Numeric Display
OK
Cancel
Copy
Paste
Add
Update
Label
Electrode + Ch
01 biceps ... biceps
02 triceps -... triceps
03 Ear - Ch... Ear
04 Ear - Cz Ear
05 Ear - Cz Ear
06 Ear - Cz Ear
Cz Raw EEG 2 µV 1 s Off Off Off
Cz AEP 10 µV 10 ms Off Off Off
Cz Trend 10 1 s Off Off Off
Define Trends
Trend label
Petes_Trend
(0 *Delta + 1 *Theta + 0 *Alpha + 0 *Beta + 0)
(1 *Delta + 1 *Theta + 1 *Alpha + 1 *Beta + 0)
OK
Cancel
Meer Hage Fre
Minder Hage F
Wave - No F
Fpz - CPz 1 s 1 mV
History P
F1: Begin
F2: Begin

FIG. 9

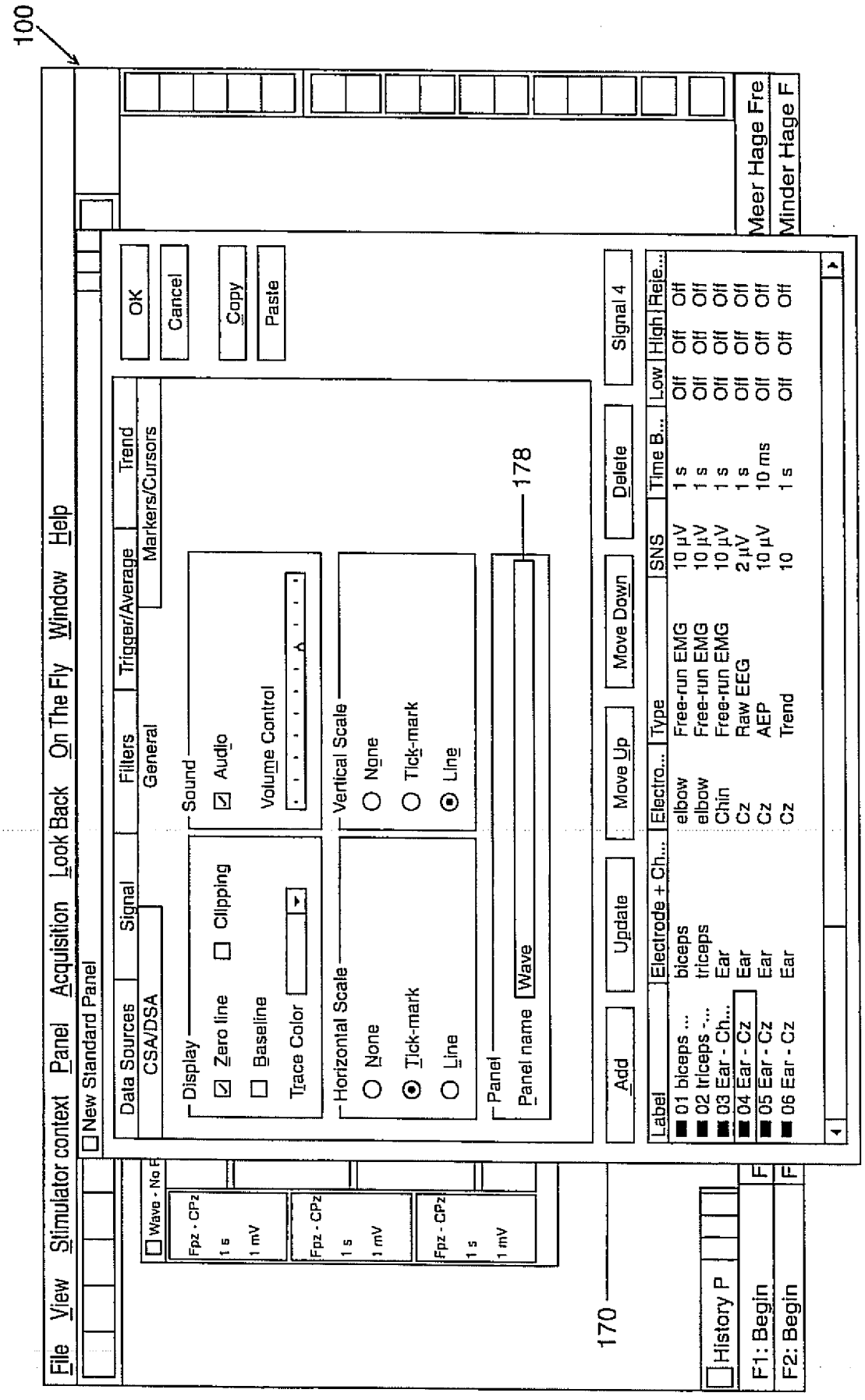
100
File View Stimulator context Panel Acquisition Look Back On The Fly Window Help
New Standard Panel
Data Sources Signal Filters Trigger/Average Trend
CSA/DSA General Markers/Cursors
OK
Cancel
Copy
Paste
Display
Zero line
Clipping
Baseline
Trace Color
Sound
Audio
Volume Control
Horizontal Scale
None
Tick-mark
Line
Vertical Scale
None
Tick-mark
Line
Panel
Panel name
Wave
178
Add
Update
Move Up
Move Down
Delete
Signal 4
Label Electrode + Ch... Electro... Type SNS Time B... Low High Reje...
01 biceps ... biceps elbow Free-run EMG 10 µV 1 s Off Off Off
02 triceps -... triceps elbow Free-run EMG 10 µV 1 s Off Off Off
03 Ear - Ch... Ear Chin Free-run EMG 10 µV 1 s Off Off Off
04 Ear - Cz Ear Cz Raw EEG 2 µV 1 s Off Off Off
05 Ear - Cz Ear Cz AEP 10 µV 10 ms Off Off Off
06 Ear - Cz Ear Cz Trend 10 1 s Off Off Off
Wave - No F
Fpz - CPz
1 s
1 mV
History P
F1: Begin
F2: Begin
Meer Hage Fre
Minder Hage F
170

FIG. 10

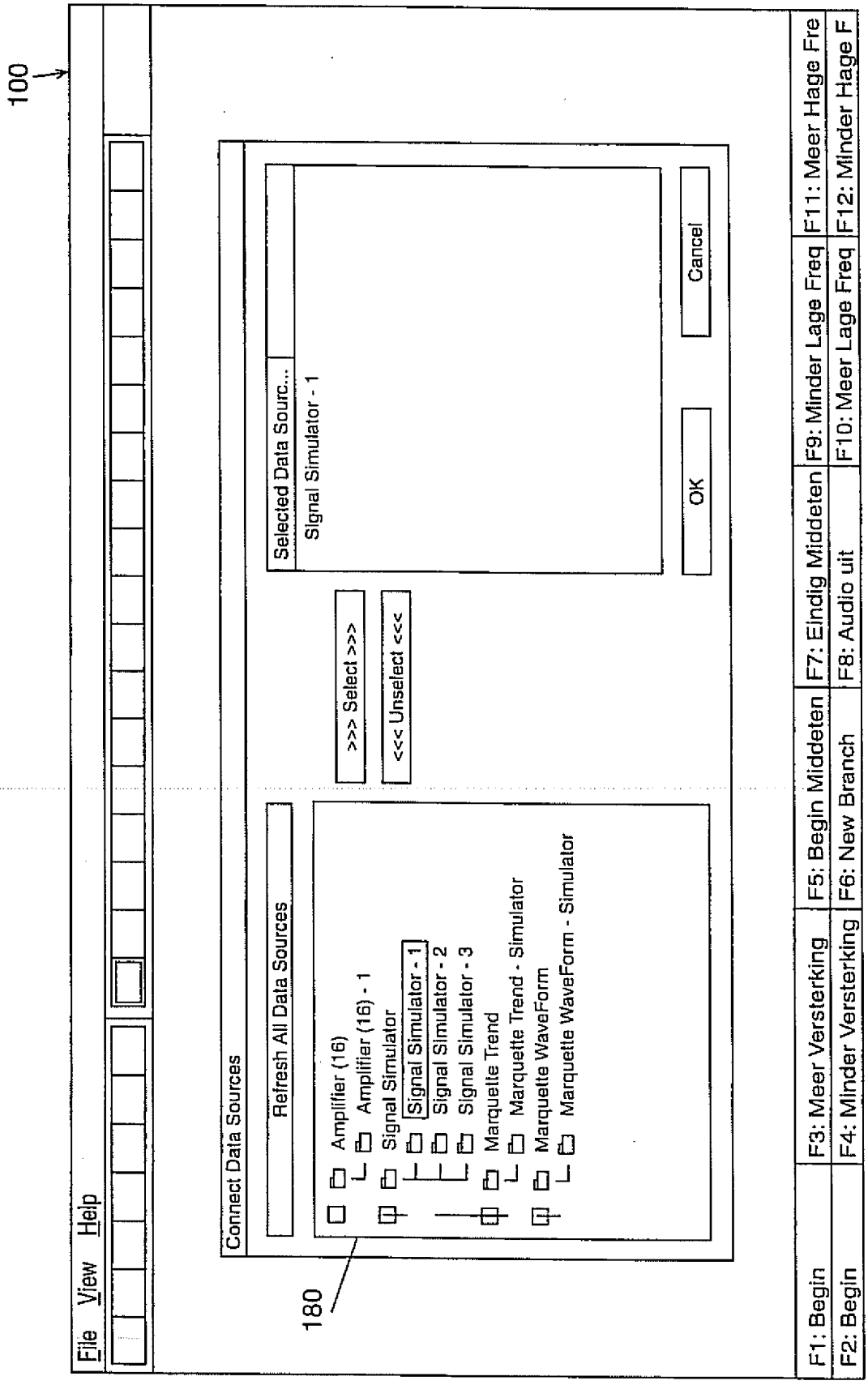
100
File View Help
Connect Data Sources
Refresh All Data Sources
Amplifier (16)
Amplifier (16) - 1
Signal Simulator
Signal Simulator - 1
Signal Simulator - 2
Signal Simulator - 3
Marquette Trend
Marquette Trend - Simulator
Marquette WaveForm
Marquette WaveForm - Simulator
180
>>> Select >>>
<<< Unselect <<<
Selected Data Sourc...
Signal Simulator - 1
OK
Cancel
F1: Begin
F2: Begin
F3: Meer Versterking
F4: Minder Versterking
F5: Begin Middeten
F6: New Branch
F7: Eindig Middeten
F8: Audio uit
F9: Minder Lage Freq
F10: Meer Lage Freq
F11: Meer Hage Fre
F12: Minder Hage F

FIG. 11

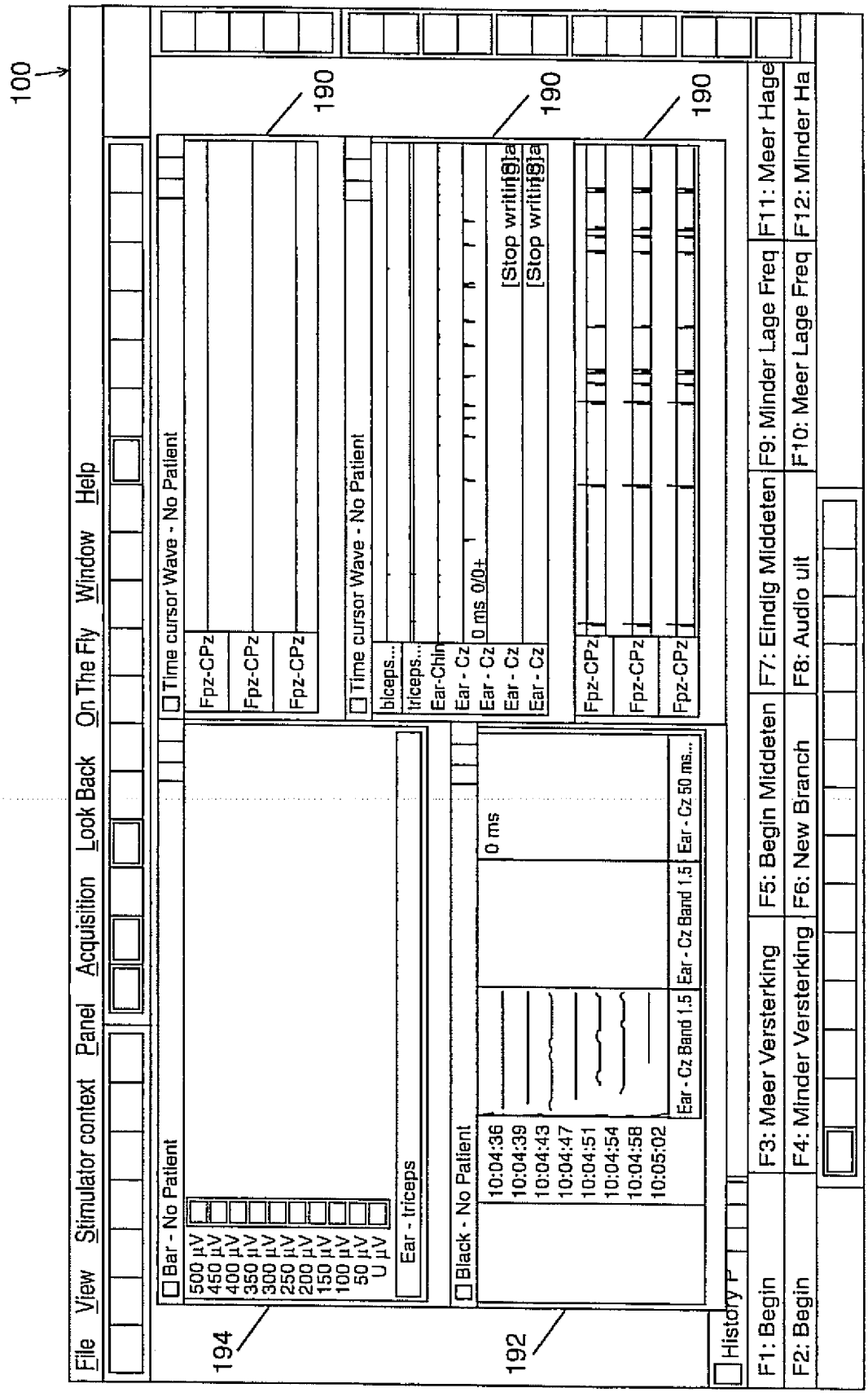
100
File View Stimulator context Panel Acquisition Look Back On The Fly Window Help
Bar - No Patient
500 µV
450 µV
400 µV
350 µV
300 µV
250 µV
200 µV
150 µV
100 µV
50 µV
0 µV
Ear - triceps
194
Black - No Patient
10:04:36
10:04:39
10:04:43
10:04:47
10:04:51
10:04:54
10:04:58
10:05:02
0 ms
Ear - Cz Band 1.5
Ear - Cz Band 1.5
Ear - Cz 50 ms...
192
History
Time cursor Wave - No Patient
Fpz-CPz
Fpz-CPz
Fpz-CPz
190
Time cursor Wave - No Patient
biceps...
triceps...
Ear-Chin
Ear - Cz
Ear - Cz
Ear - Cz
0 ms 0/0+
[Stop writing]a
[Stop writing]a
190
Fpz-CPz
Fpz-CPz
Fpz-CPz
190
F1: Begin
F2: Begin
F3: Meer Versterking
F4: Minder Versterking
F5: Begin Middeten
F6: New Branch
F7: Eindig Middeten
F8: Audio uit
F9: Minder Lage Freq
F10: Meer Lage Freq
F11: Meer Hage
F12: Minder Ha

FIG. 12

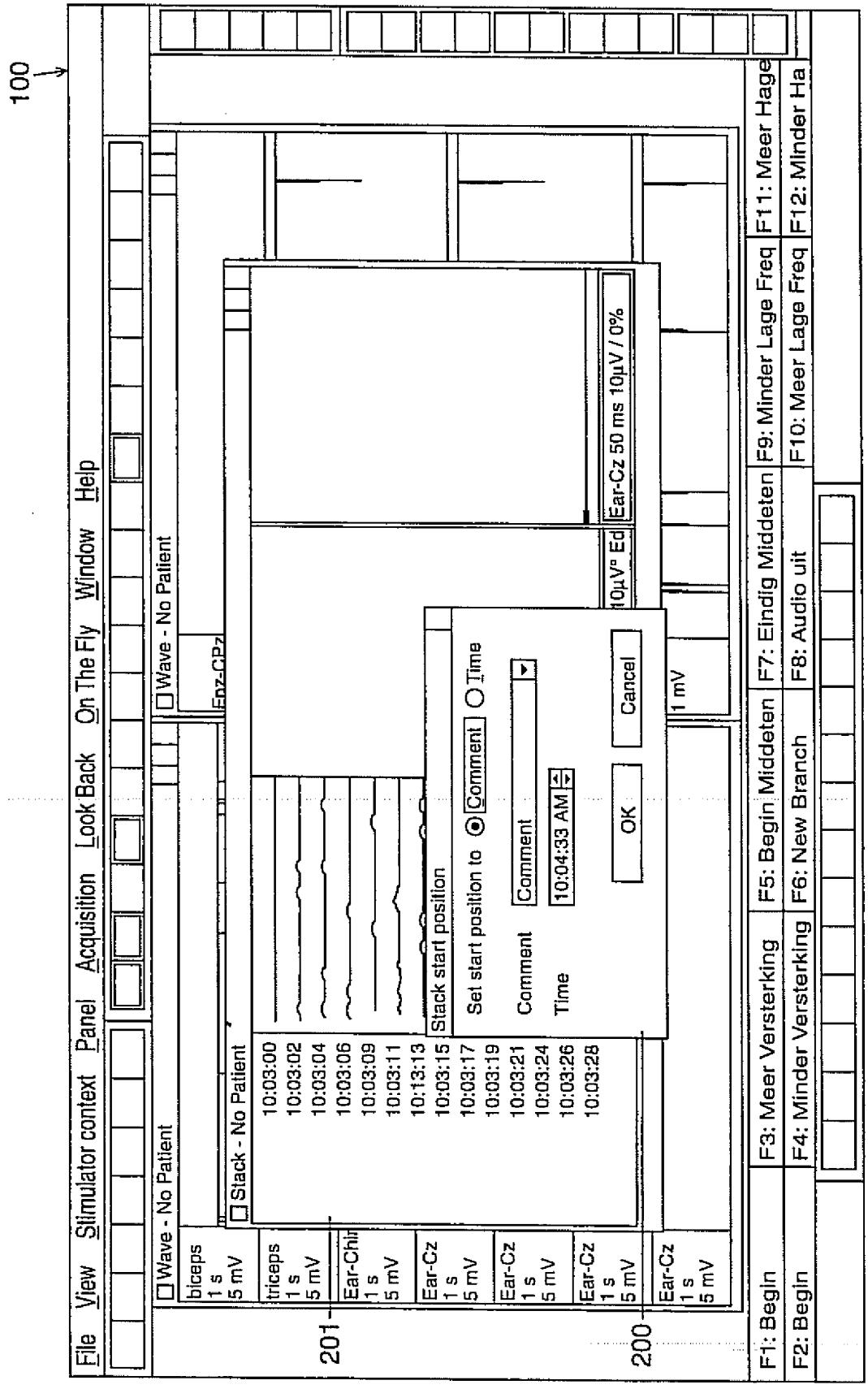
100
File View Stimulator context Panel Acquisition Look Back On The Fly Window Help
Wave - No Patient
Stack - No Patient
Wave - No Patient
Enz-CPz
biceps 1 s 5 mV
triceps 1 s 5 mV
Ear-Chin 1 s 5 mV
Ear-Cz 1 s 5 mV
Ear-Cz 1 s 5 mV
Ear-Cz 1 s 5 mV
Ear-Cz 1 s 5 mV
10:03:00
10:03:02
10:03:04
10:03:06
10:03:09
10:03:11
10:13:13
10:03:15
10:03:17
10:03:19
10:03:21
10:03:24
10:03:26
10:03:28
Stack start position
Set start position to Comment Time
Comment
Time
Comment
10:04:33 AM
OK
Cancel
10µV° Ed
Ear-Cz 50 ms 10µV / 0%
1 mV
201
200
F1: Begin
F2: Begin
F3: Meer Versterking
F4: Minder Versterking
F5: Begin Middeten
F6: New Branch
F7: Eindig Middeten
F8: Audio uit
F9: Minder Lage Freq
F10: Meer Lage Freq
F11: Meer Hage
F12: Minder Ha

FIG. 13

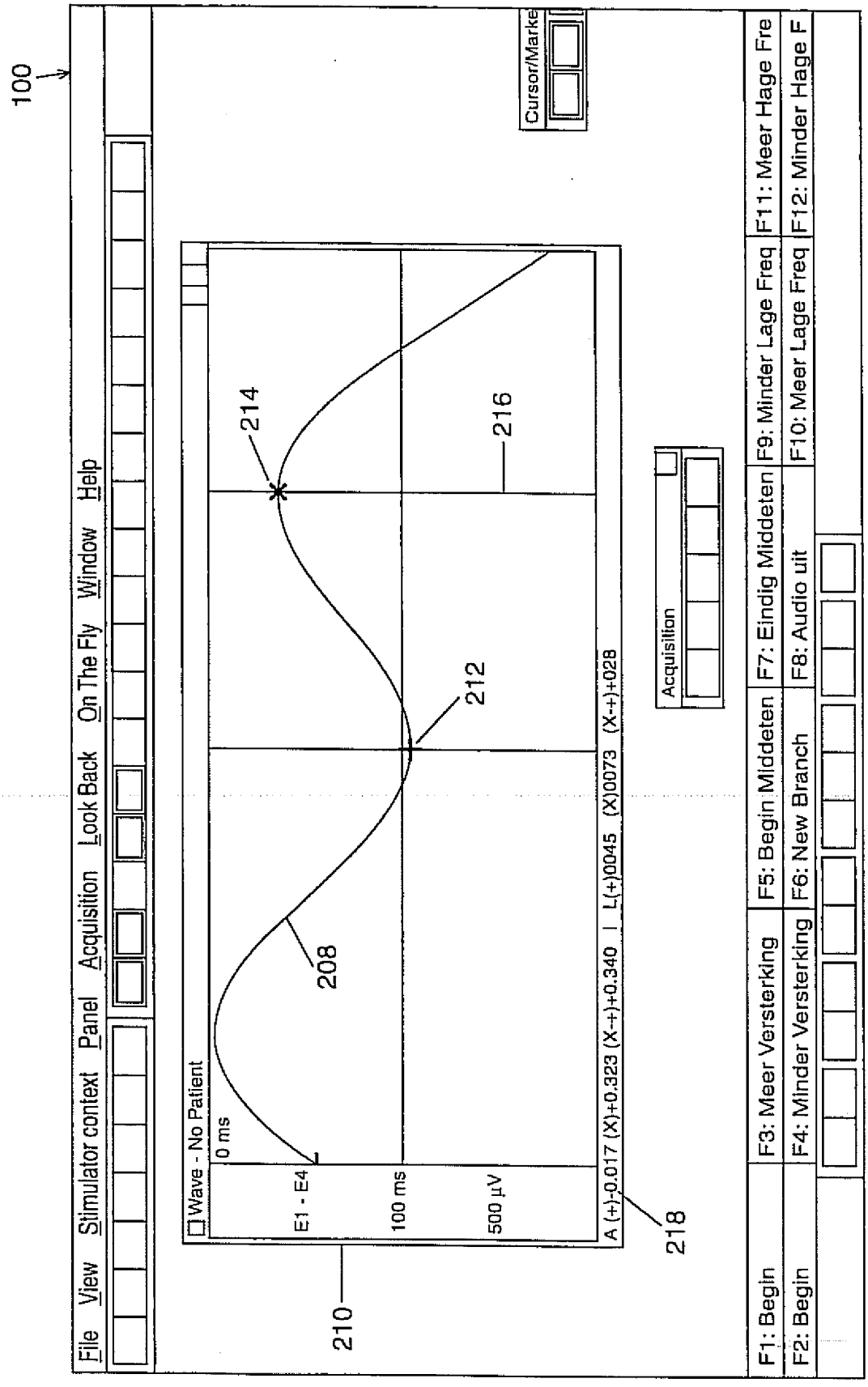
100
File View Stimulator context Panel Acquisition Look Back On The Fly Window Help
Wave - No Patient
0 ms
E1 - E4
100 ms
500 µV
A (+)-0.017 (X)+0.323 (X-+)+0.340 | L(+)0045 (X)0073 (X-+)+028
208
210
212
214
216
218
Cursor/Marke
Acquisition
F1: Begin
F2: Begin
F3: Meer Versterking
F4: Minder Versterking
F5: Begin Middeten
F6: New Branch
F7: Eindig Middeten
F8: Audio uit
F9: Minder Lage Freq
F10: Meer Lage Freq
F11: Meer Hage Fre
F12: Minder Hage F

FIG. 14

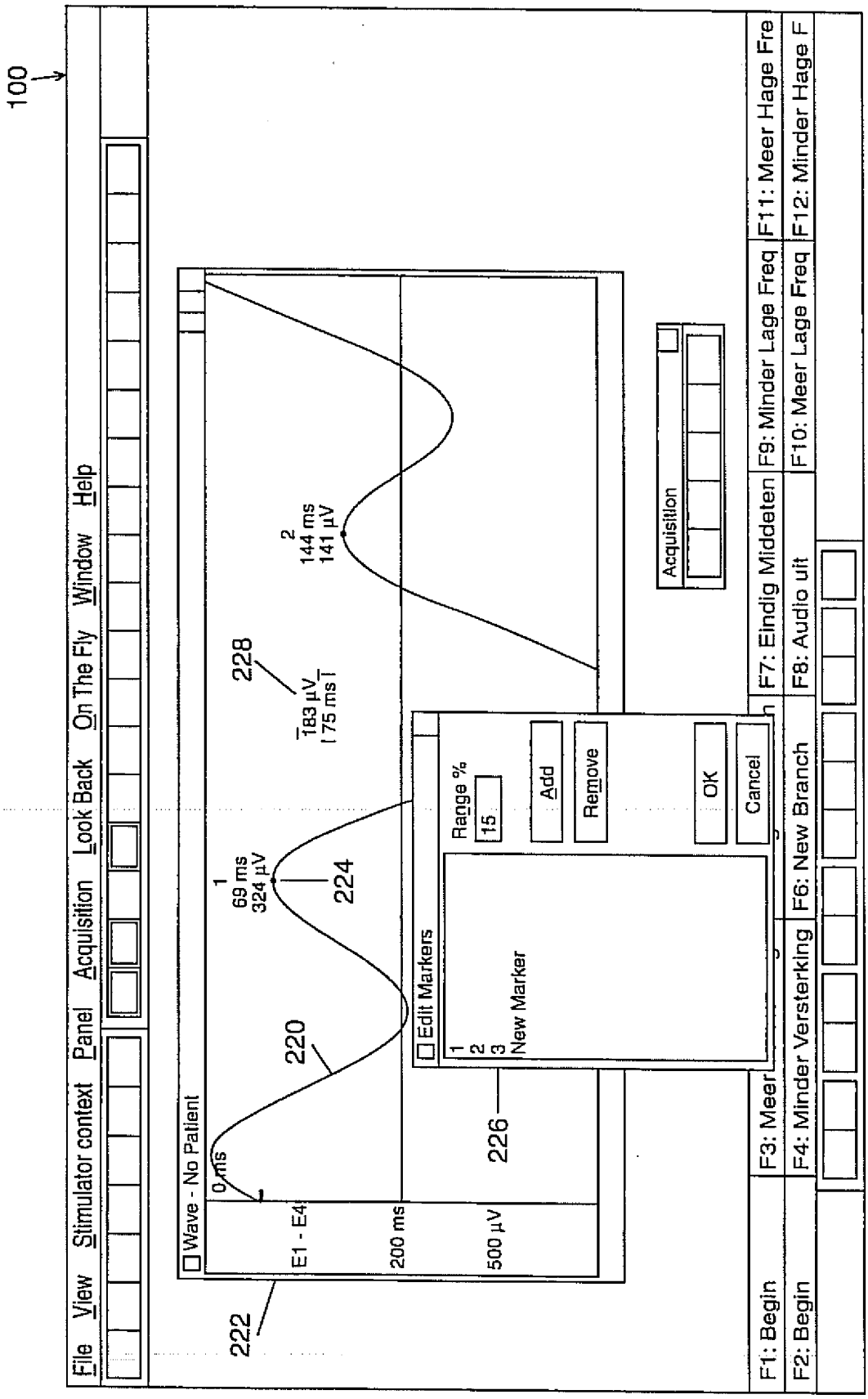
100
File View Stimulator context Panel Acquisition Look Back On The Fly Window Help
Wave - No Patient
E1 - E4
200 ms
500 µV
0 ms
1
69 ms
324 µV
2
144 ms
141 µV
183 µV
175 ms
220
222
224
226
228
Edit Markers
Range %
15
Add
Remove
OK
Cancel
1
2
3
New Marker
Acquisition
F1: Begin
F2: Begin
F3: Meer
F4: Minder Versterking
F6: New Branch
F7: Eindig Middelen
F8: Audio uit
F9: Minder Lage Freq
F10: Meer Lage Freq
F11: Meer Hage Fre
F12: Minder Hage F

FIG. 15

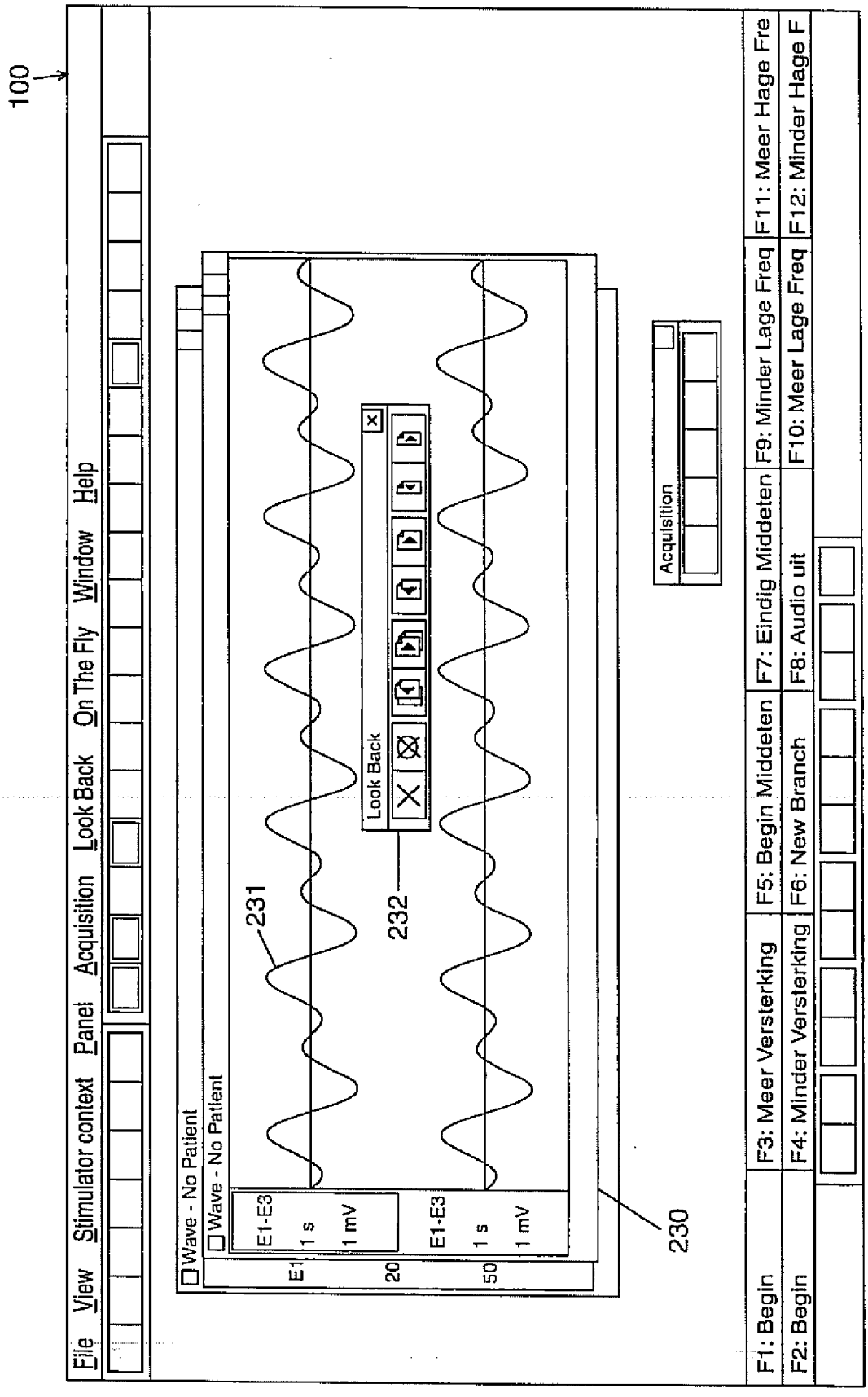
100
File View Stimulator context Panel Acquisition Look Back On The Fly Window Help
Wave - No Patient
Wave - No Patient
E1-E3
1 s
1 mV
E1
20
E1-E3
1 s
1 mV
50
231
232
Look Back
Acquisition
230
F1: Begin
F2: Begin
F3: Meer Versterking
F4: Minder Versterking
F5: Begin Middeten
F6: New Branch
F7: Eindig Middeten
F8: Audio uit
F9: Minder Lage Freq
F10: Meer Lage Freq
F11: Meer Hage Fre
F12: Minder Hage F

FIG. 16

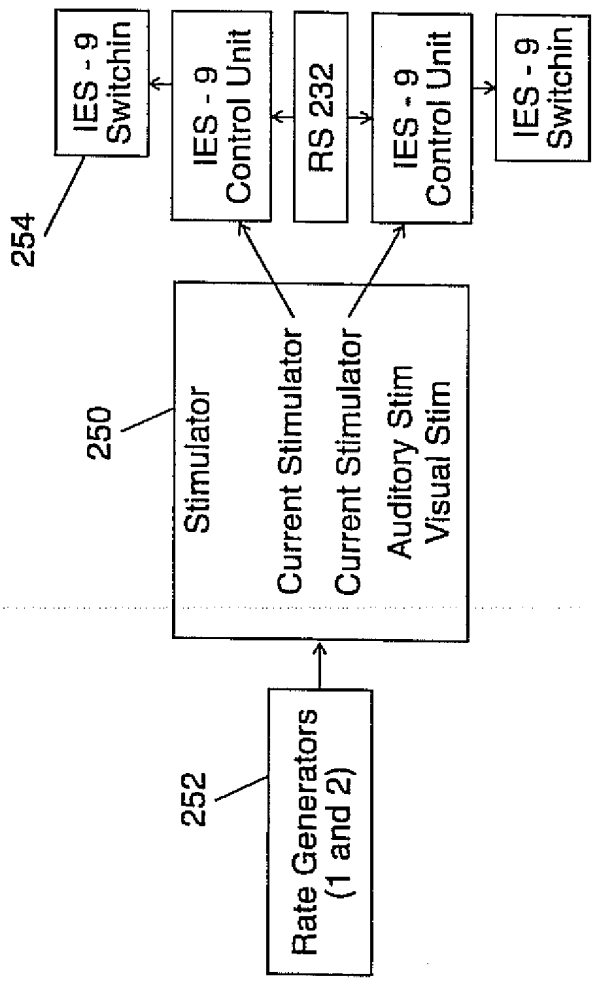
IES - 9 Switchin
IES - 9 Control Unit
RS 232
IES - 9 Control Unit
IES - 9 Switchin
254
250
Stimulator
Current Stimulator
Current Stimulator
Auditory Stim
Visual Stim
252
Rate Generators (1 and 2)

FIG. 17

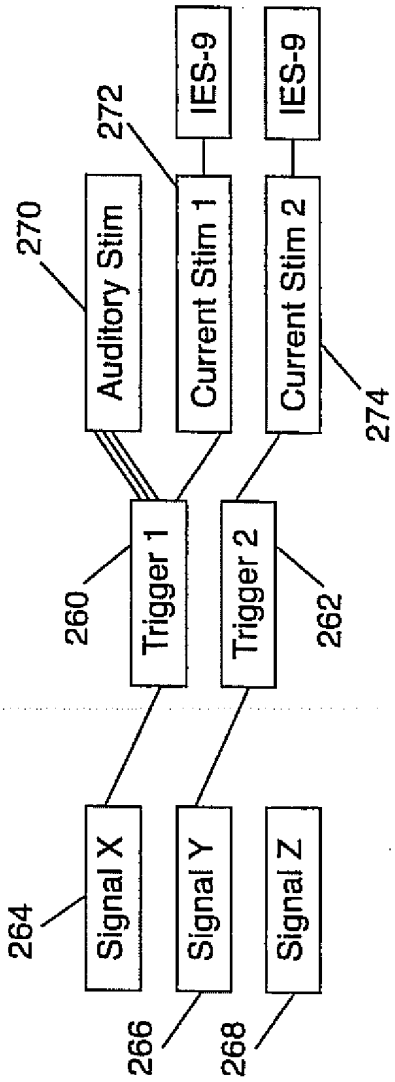
IES-9
IES-9
272
270
Auditory Stim
Current Stim 1
Current Stim 2
274
260
Trigger 1
Trigger 2
262
264
Signal X
Signal Y
Signal Z
266
268

FIG. 18

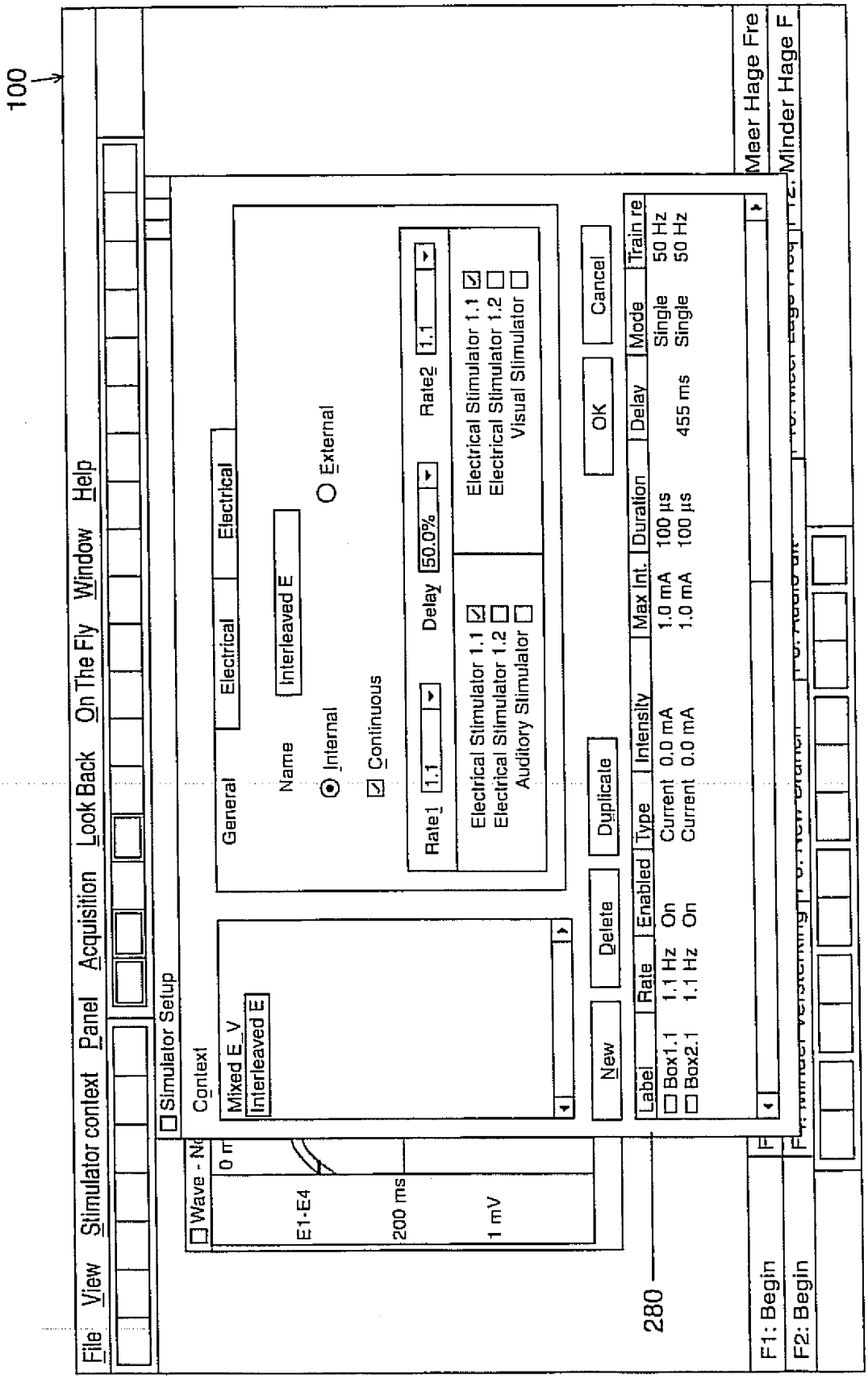
100
File View Stimulator context Panel Acquisition Look Back On The Fly Window Help
Simulator Setup
Context
Mixed E_V
Interleaved E
General
Electrical
Electrical
Name
Interleaved E
Internal
External
Continuous
Rate1 1.1
Delay 50.0%
Rate2 1.1
Electrical Stimulator 1.1
Electrical Stimulator 1.2
Auditory Stimulator
Electrical Stimulator 1.1
Electrical Stimulator 1.2
Visual Stimulator
OK
Cancel
New
Delete
Duplicate
Label Rate Enabled Type Intensity Max Int. Duration Delay Mode Train re
Box1.1 1.1 Hz On Current 0.0 mA 1.0 mA 100 µs Single 50 Hz
Box2.1 1.1 Hz On Current 0.0 mA 1.0 mA 100 µs 455 ms Single 50 Hz
Wave - Ne
E1-E4
200 ms
1 mV
280
F1: Begin
F2: Begin
Meer Hage Fre
Minder Hage F

FIG. 19

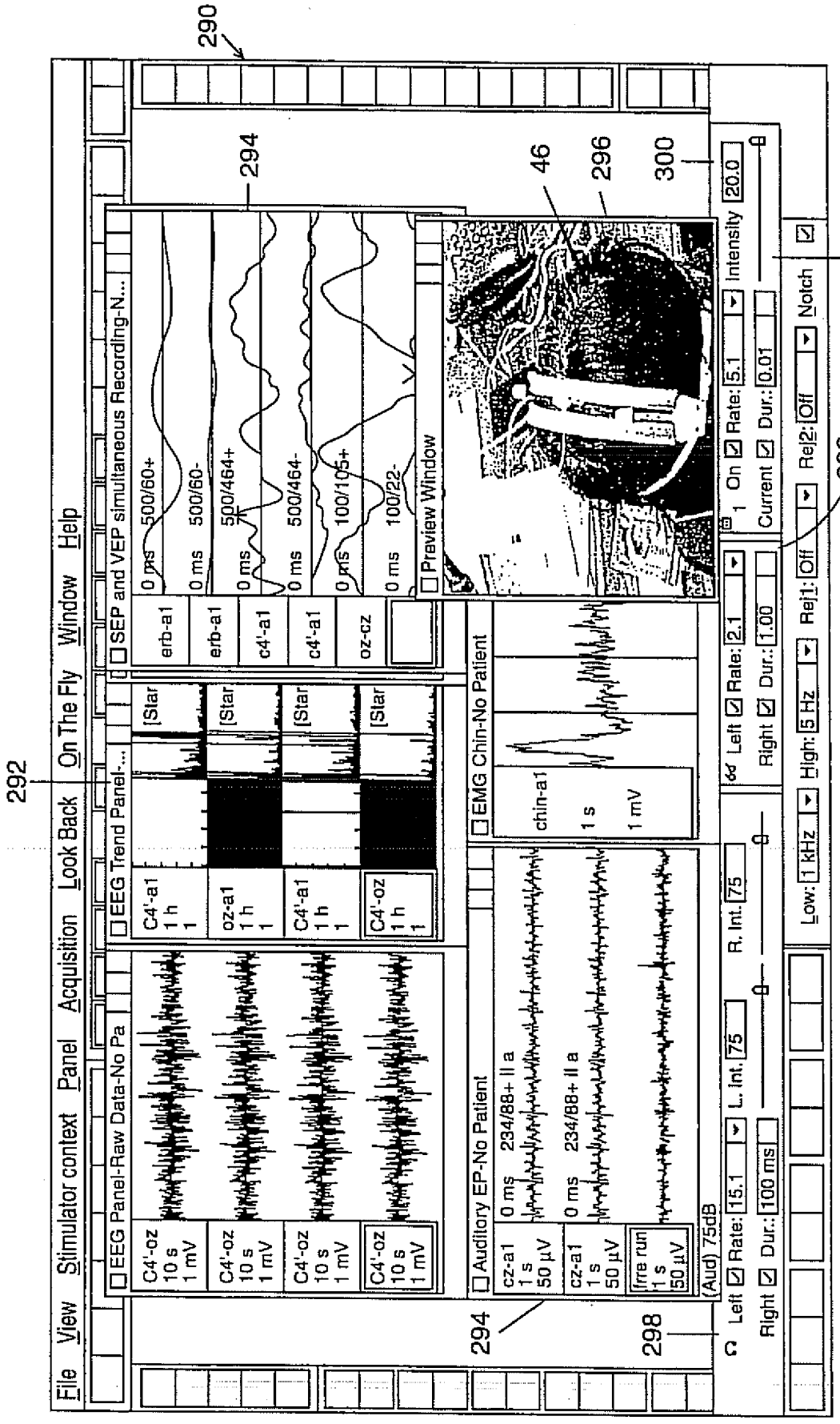
290
292
294
46
296
300
299
298
File View Stimulator context Panel Acquisition Look Back On The Fly Window Help
EEG Panel-Raw Data-No Pa
EEG Trend Panel-...
SEP and VEP simultaneous Recording-N...
Auditory EP-No Patient
EMG Chin-No Patient
Preview Window
Left Rate: 15.1 L. Int. 75 R. Int. 75
Right Dur.: 100 ms
Left Rate: 2.1
Right Dur.: 1.00
On Rate: 5.1 Intensity 20.0
Current Dur.: 0.01
Low: 1 kHz High: 5 Hz Rej1: Off Rej2: Off Notch

FIG. 20

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/10571

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61B 5/00
US Cl. :600/300

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/372, 382, 383, 481, 483

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,724,032 A (KLEIN et al.) 03 March 1998, entire document.	1-24
A	US 5,724,025 A (TAVORI) 03 March 1998, entire document.	1-24

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"P" document published prior to the international filing date but later than the priority date claimed

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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Date of the actual completion of the international search	Date of mailing of the international search report
09 JUNE 2000	12 JUL 2000
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer RYAN CARTER Telephone No. (703) 308-2990

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International Bureau

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(75) Inventor/Applicant *(for US only)*: HADAS, Noam [IL/IL]; P.O. Box 14014, 14014 Tel Aviv (IL).

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(54) Title: A NOCTURNAL MUSCLE ACTIVITY MONITORING SYSTEM

(57) Abstract

A muscle activity monitoring system. The system includes a muscle activity sensor, for sensing muscle activity at a location in the body, a processor for analyzing the sensed muscle activity to determine the presence of a pattern of muscle activity, and for correlating the pattern of muscle activity with a diagnosis. The system also includes a display for displaying the diagnosis, a power source for powering the muscle activity sensor, the processor and the display. The system also includes a housing for housing the processor, the display, the power source and the muscle activity sensor. The housing is placed at the location on the body.

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A NOCTURNAL MUSCLE ACTIVITY MONITORING SYSTEM

FIELD AND BACKGROUND OF THE INVENTION

The present invention relates to medical monitoring devices and, in particular, it relates to a monitor for the detection of disorders of nocturnal skeletal muscle activity.

It is known that nocturnal skeletal muscle activity disorders are a common medical problem. Two such syndromes of this nature are bruxism (nocturnal teeth grinding) and Periodic Leg Movement Syndrome (PLMS).

Surveys show that over 5% of the adult population suffer from bruxism. In this condition, ongoing involuntary grinding of the teeth damages healthy enamel on the chewing surfaces of the teeth (possibly even causing stress fractures), and may cause damage to the tempero-mandibular joint. As such, Bruxism is a far more destructive process than is dental caries. However, only a minority of patients suffering from bruxism are aware of their condition. Usually, the patient is completely unaware of this disorder, and does not seek medical or dental attention until irreversible damage to their dentition has occurred, necessitating extensive restorative treatment or tooth extraction. "Clenching" is a common variation of bruxism, and involves the non-purposeful closing of teeth in the chewing position. Both bruxism and clenching can occur during the day, but in most cases occur at night during sleep.

Periodic Leg Movement Syndrome (PLMS) is a common sensorimotor sleep disorder in which repeated involuntary, highly regular, jerky movements occur periodically, every 20 to 40 seconds, in one or both legs during sleep. PLMS may occur as an isolated phenomenon, but more often is associated with other sleep disorders such as Restless Leg Syndrome (RLS), narcolepsy, or sleep apnea. Surveys show that about 1% of the population over 40 years of age have either PLMS or RLS, and that the prevalence of the disorder increases with age. PLMS may also be associated with systemic diseases such as iron deficiency anemia, kidney failure, diabetes, rheumatoid arthritis, and peripheral neuropathy. PLMS and RLS may lead to severe sleep disruption and excessive daytime somnolence. As such, the patient may easily fall asleep during working hours, such as when the patient is driving a car or a

truck

Definitive diagnosis of bruxism can be achieved by recording jaw muscle electromyographic (EMG) signals during sleep. So too, PLMS is best diagnosed by monitoring the EMG activity of the Tibialis Anterior (calf) muscle while the patient is sleeping. Both such EMG studies are often part of an in-lab, full night, formal sleep study. In such a study, the patient is required to sleep for a whole night in a controlled environment (a "sleep laboratory") while connected to multiple monitoring devices, which continuously measure such physiological parameters as respiratory effort, nasal and oral airflow, brain electrical activity (EEG), Tibialis Anterior or jaw muscle EMG activity, heart rate and rhythm (ECG), and blood oxygen saturation. These parameters are recorded on paper or stored in a memory bank for later analysis. A trained sleep technician is required to oversee the study so as to ensure that all parameters are recorded properly. The data is then analyzed, either manually or by specialized software, to produce a "hypnogram" which describes the nature of the patients sleep. Indices in the hypnogram, such as a "bruxism index" and a "leg movement index", are then used, by a sleep specialist, to diagnose the patients pathology, and its severity.

Bruxism is initially treated with an "occlusal splint" bite guard, or by biofeedback techniques, however ongoing monitoring of the efficacy of treatment is necessary so as to determine if and when more aggressive medical or dental intervention is required. PLMS is managed with medications such as benzodiazepines, anti-dopaminergic agents, or opioids. Multiple trials of therapy may be necessary before the optimal drug and dosage is found, and a medication that is initially effective may lose its efficacy with repeated use. Thus PLMS, too, requires ongoing monitoring of the efficacy of treatment.

The formal sleep study as a means of diagnosing and following-up patients with sleep-related problems, however, suffers from several deficiencies and limitations:

1. The study requires the use of multiple medical monitoring devices and the continuous presence of a trained technician. It is thus labor intensive to perform, and requires the use of multiple, expensive, resources. As such, sleep laboratories themselves are a limited resource, each containing only a limited number of beds. This is particularly problematic as studies are often conducted on "suspicious"

patients, in whom the outcome is frequently negative. In such patients, for whom there was no need for the study at all, a limited screening study may have been sufficient to exclude sleep pathology. In addition, the study price often prohibits repeating studies on a regular basis for purposes of patient follow-up, and prohibits performing multiple studies for the screening of large populations.

2. The patient is asked to sleep in an unnatural sleep environment, which may itself affect his sleep patterns.

3. The patient is inconvenienced by having to be in a hospital setting for a night.

4. There is no patient privacy.

In order to overcome some of these drawbacks, the performance of home studies by means of ambulatory systems has become popular. These studies utilize miniature ambulatory recorders, and are sometimes limited to a relatively small number of information recording channels. The patient is prepared for the study at the sleep lab, and returns home with all sensors appropriately attached. Alternatively, a technician may come to the patient's home, or the patient may attach the sensors by himself after receiving appropriate instruction from a technician. The study is then conducted in the patient's home, as he sleeps in his own bed, and the recorded data stored in a memory device. In the morning the recorder and memory device are returned to the sleep lab for data downloading to an analysis station. Some of these ambulatory systems can correct for some data recording problems, by adjusting the gain or filtering during data recording or when post-processing the data. Alternatively, the study can be monitored from the sleep lab via a modem.

Although ambulatory sleep-monitoring systems are much more convenient to the patient, and considerably less expensive than formal, in-lab, sleep studies, all current ambulatory sleep-monitoring systems suffer from several deficiencies:

1. Performance of the study still requires the participation of a trained technician (for the purposes of either attaching the monitoring device or instructing the patient how to do so) and the participation of a formal sleep laboratory (for the purposes of downloading and analyzing the test results, and maintaining the equipment necessary for the performance of the test). Such tests are thus still labor and

resource intensive.

2. As analysis of the recorded data is performed off-line in the sleep laboratory, the ambulatory monitoring device must be able to store all registered data in a suitable memory storage device, until such data can be downloaded. Alternatively, if the data is relayed to the sleep laboratory in real time, a modem and telephone line are necessary. Current ambulatory devices are therefore relatively complex and expensive to manufacture. As such, ambulatory studies are still too expensive to perform on a regular basis (currently approximately $500 per study), thus precluding their widespread use as a screening tool or for purposes of frequent patient follow-up. In addition, the cost of such studies does not justify their use on "difficult" patients, such as mental health patients or small children, in whom the likelihood of technical failure of the study is high.

There is therefore a need for a nocturnal skeletal muscle activity disorder screening system that is suitable for widespread use for patient screening and follow-up. Such a system should be sufficiently simple to implement as to allow patients to perform the study at home, without the need for assistance from a trained technician. In addition, such a system should provide the patient with an easily understandable result at the end of the study, without the need for data processing at a sleep laboratory, and without the need for interpretation of the result by a physician or technician. Finally, such a system should be sufficiently inexpensive as to make multiple and frequent studies, for purposes of monitoring and follow-up, practical to finance.

SUMMARY OF THE INVENTION

The present invention is an ambulatory nocturnal muscle activity monitoring system. The invention integrates a minimal data-collection and analysis system into a disposable, single use device that achieves data-collection and analysis in real time, and outputs the study result in an easily understood format immediately following the study.

The entire system is incorporated into a single small, flexible, plastic unit which can be easily positioned, or placed, on the muscle group under study. The system is powered by a lithium, or similar, battery, which is irreversibly activated by means of the patient pulling on a tab. Once activated, electrodes input myoelectric data describing the pattern of muscle activity into a micro-processor, via an analog to digital converter. A flashing LED display indicates to the user that the device is functioning properly. A software module detects specific patterns of electromyographic activity and, together with real-time clock information, the presence of episodes of abnormal muscle activity is documented. After a predefined period of time, non volatile output flags (in the form of miniature electro-chemical cells, or heat sensitive colored dots) are set by the software, each output flag describing a specific study outcome. Once activated, the output flags undergo a permanent color change. As such, they produce an easily-read hard copy of the study results, informing the user whether significant abnormal muscle activity was detected and whether a physician need be consulted. Hereinafter, output flags which undergo a permanent change in color when activated by heat are referred to as "heat sensitive permanent color display elements", and output flags which undergo a permanent change in color when activated by an electro-chemical process are referred to as "electro-chemical permanent color display elements".

The integration, onto an EMG sensor, of a muscle activity monitoring system which is capable of analyzing EMG data in real time and generating an immediate report thereof, is unique to the current invention. By "real time" is meant that the sensing of muscle activity and the processing of such sensed EMG data occur during the same time interval, or within a few seconds of each other, rather than the processing occurring after all muscle activity sensing has been completed.

As data is analyzed in real time, the need for a large memory storage unit to store data for later analysis, and the need for complex downloading hardware, are obviated. This feature allows the entire system to be manufactured in a small and inexpensive format, and provides the user with the result of the study immediately upon conclusion of the study, without the need for data processing and analysis by medical professionals at a sleep laboratory. Furthermore, as the power source, processor, and display mechanism of the device are all integrated with the EMG probe

(or sensor) into a single small unit (without the need for cables or wires connecting these components to each other), and as an easily-seen flashing light confirms for the user that placement and operation of the device are correct, the device is simple and straightforward to use. The device can thus be operated without supervision by trained medical professionals. Accordingly, the cost per study is sufficiently low as to justify performing studies frequently for screening purposes (whenever there is even a slight chance of true pathology being present) or for regular patient follow-up. As there are no cables or wires connecting the EMG sensor with the rest of the device, the possibility that the sensor might be pulled off of the users body, due to the cable becoming entangled while the user is asleep, is obviated.

According to the teachings of the present invention there is provided a muscle activity monitoring system, including a muscle activity sensor, for sensing muscle activity at a location on a body; a processor, for analyzing the sensed muscle activity to determine the presence of a pattern of muscle activity, and for correlating the pattern of muscle activity with a diagnosis; a display, for displaying the diagnosis; a power source, for powering the muscle activity sensor, the processor, and the display; and a housing, for housing the processor, the display, and the power source, on the muscle activity sensor, the housing being placeable at the location on the body. There is also provided a muscle activity monitoring method, including the steps of placing a housing at a location on a body; sensing muscle activity at the housing during a time interval; processing the sensed muscle activity to detect a pattern of muscle activity, the processing occurring during the time interval; correlating the pattern of muscle activity with a diagnosis, the correlating occurring during the time interval; and displaying the diagnosis on the housing. There is also provided an electrochemical display system, including a cathode; an anode, and a layer of electro-conductive material covering at least part of the anode, the layer being operative to undergo an electrochemical process when electric current flows from the anode to the cathode, and wherein the electrochemical process eventuates in a change in a perceived color of the anode. There is further provided a method of irreversible display, including providing a cathode and an anode, the anode being at least partially covered by an electro-conductive material; inducing a flow of electrical current between the cathode and the anode, thereby effecting an electrochemical process in the electro-conductive

material, and thereby causing a change in a perceived color of the anode.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is herein described, by way of example only, with reference to the accompanying drawings, wherein:

FIG. 1 is a line drawing of the physical structure of the current invention;

FIG. 2 is a block diagram of the electrical components of the current invention;

FIG. 3 is a block diagram describing the data input to, and data flow within, the CPU of the current invention;

FIG. 4 is a cross-section through an unactivated electro-chemical display unit suitable for use in the current invention;

FIG. 5 is a cross-section through an activated electro-chemical display unit suitable for use in the current invention, and

FIG. 6 is a line drawing of two electro-chemical display units, demonstrating possible formats for displaying study outcomes.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is a nocturnal muscle activity monitoring system.

The principles and operation of a nocturnal muscle activity monitoring system, according to the present invention, may be better understood with reference to the drawings and the accompanying description.

Referring now to the drawings, Figure 1 is a line drawing of the physical structure of the current invention.

A muscle activity monitoring device **8** is depicted in Fig. 1. Device **8** is positioned, by the user, on the skin overlying the muscle group under study, for example the temporalis or masseter muscles (if bruxism is suspected) or the tibialis anterior muscles (if PLMS is suspected). A thin, flexible housing **6**, shaped like a thin strip, serves as a base for the electronic components of device **8**. In the preferred embodiment, housing **6** is made of a flexible plastic polycarbonate film approximately 0.1 mm thick, and is oval shaped. The length of housing **6** is approximately three

inches and it's width one inch. A cover 2, made of a similar material as housing 6, is located on top of housing 6 so as to form a miniature box containing all hardware and electrical components of device 8. A power source (not shown), in the form of a flat lithium battery, is housed in the miniature box on housing 6, and powers the functioning of all elements of device 8. One of the contacts of the power source is insulated from a conductive electrode (not shown) on housing 6 by a pull-tab 1. When tab 1 is pulled out by the user, contact is made with the power source and the electrode, thus completing the electrical circuit, and operation of device 8 commences. Two conductive electrodes 7 and 9 are located on the opposite side of housing 6 to that of cover 2, and are covered with an adhesive gel which allows for the comfortable attachment of device 8 to the skin overlying the muscle group under study. Electrodes 7 and 9 are standard EMG electrodes (metal buttons 10mm in diameter coated with a silver/silver-chloride ($AgCl_2$) layer) and attach to the skin by means of a pad of conductive gel, which contains water and salts. Electrodes 7 and 9 are connected to the input of an amplifier and analog-to-digital convertor and microprocessor (not shown), which are housed under cover 2. During operation of device 8, electrodes 7 and 9 sense myoelectric activity generated by the muscle group under study, whenever such muscle group contracts or relaxes. The signals so generated are processed by the microprocessor housed under cover 2, so as to detect patterns of EMG activity that are diagnostic of the muscle activity disorder being screened for (for example, bruxism or PLMS). A LED display 3 is located on cover 2 such that it can be easily seen by the user, either when looking in a mirror or when looking directly at device 8, once the system has been attached to the skin overlying the muscle group under study and operation commenced. LED 3 is operative to flash when a maximum EMG signal is detected immediately after turn-on, and thereafter flashes whenever an EMG signal over a predefined threshold (depending on the type of disorder being screened for) is detected by the microprocessor. The flashing of LED 3 indicates that proper placement of electrodes 7 and 9 has been achieved and that the system is functioning properly.

One (or more) non-volatile markers 4 are located on base 6 alongside cover 2. Together, markers 4 constitute a display component of device 8, and hereinafter, such markers are also referred to as "display elements". In a first preferred embodiment of

the display component of device **8**, markers **4** are electro-chemical cells which are located under a gel cover **5**. When current is passed though one of the cells, an electro-chemical reaction induces a permanent color change in one of the electrodes. This embodiment of the display component of device **8** is described in detail in figures 4, 5 and 6 below. In a second preferred embodiment of the display component of device **8**, each one of markers **4** comprises a miniature heating element, and a coating of a heat sensitive material. In this embodiment, markers **4** are not covered by gel cover **5**. When current is passed though one of the heating elements it heats up, inducing a change in the color of the coating material (such as rendering the coating material permanently black). This color change is permanent, even after cooling down of the element.

When the muscle activity study is complete, the microprocessor (CPU) issues a command to flow an electric current through one (or more) of non-volatile markers **4**. The choice of which of markers **4** to activate depends on the study conclusion, as determined by the CPU. Each non-volatile marker **4** corresponds to one of several possible diagnoses. By "diagnoses" is meant possible study outcomes describing the pattern of abnormal muscle activity detected while the subject was sleeping. As the color change induced in marker **4** is permanent, upon awakening the user is able to immediately see the result of the study, and marker **4** serves as a permanent "hard-copy" of the result of the study.

In FIG. 2, a simplified block diagram of the electrical components of device **8** is shown. Electrodes **7** and **9** input EMG data, in the mV range, to a band pass filter and low-noise, high gain amplifier **14** which amplifies the signal. Output from amplifier **14** is converted to a digital signal by an A/D (analog to digital) converter **12**. The resultant digital data stream is input to a CPU **10**, which runs specialized data acquisition and analysis software. A/D converter **12** may be part of CPU **10**. CPU **10** analyses the signal in real time by taking a sample each 1mSec, calculating the envelope amplitude of the signal, and detecting significant peaks in this value. CPU **10** causes LED **3** to flash each time a noticeable signal peak lasting over 0.5 seconds is detected. Signal maxima are counted by CPU **10** for the duration of the study, and when a conclusion is reached at the end of the study, CPU **10** outputs a command to one of non-volatile markers **4**, thereby permanently changing its color. The entire

device is powered by a power source 16, usually a Lithium battery.

In an alternative embodiment, a bruxing signal is derived from a strain gauge or other movement sensor located over the masseter or temporalis muscles, rather than from electrodes 7 and 9. In this embodiment, muscle bruxism exerts a force on the strain gauge, thereby changing its resistance. The change in resistance is then used as the input data to CPU 10. In this embodiment, signal amplification and integration are not required.

FIG. 3 describes the data input to, and data flow within, CPU 10. Raw EMG signals from skin surface EMG electrodes 7 and 9 are smoothed, amplified and converted to digital format by amplifier 14 and A/D converter 12. Amplifier 14 and A/D converter 12 are hereinafter together referred to as a signal conditioner. The resultant digital data, reflecting total muscle activity caused by neural stimulation of the muscle, is input to an envelope detection module 18. Envelope detection module 18 calculates the envelope waveform of the high frequency components of the input data. The output from envelope detection module 18 is fed to a valid muscle contraction detection module 20. Immediately after turn-on, valid muscle contraction detection module 20 identifies a predefined pattern of maximum signal amplitude values (depending on the muscle group under study, as described below), and inputs these values to a reference peak memory 22, where such values are stored. After this initial period of reference peak value generation, valid muscle contraction detection module 20 monitors the data generated by envelope detection module 18, locates the maximum signal amplitude in the data, and compares that value to the stored reference maximum which had been measured immediately after device turn on and stored in reference peak memory 22. Sliding window integration is used for quantitative analysis of the signal and for locating maximal signal amplitude, which is compared to the maximum EMG signal sampled at turn on. An abnormal muscle contraction is marked if the signal amplitude exceeds a predefined limit (depending on the muscle group under study). For bruxism screening an abnormal muscle contraction is marked whenever the signal amplitude is at least 50% of the reference peak value. For PLMS screening, an abnormal muscle contraction is marked whenever the signal amplitude is at least 70% of the reference peak value. An episode detection module 24 calculates the time between consecutive abnormal muscle

contractions, and counts the number of such contractions. If the temporal parameters of a train of contractions are within the defined limits for PLMS, one count is added to an episode counter module **26**. For bruxing, a simple count of activity peaks is sufficient.

The entire study timing and duration is controlled by a system controller module **28**. System controller module **28** runs a reference peak value detection loop until three distinct peaks are detected after turn-on, initiates continuos data sampling thereafter, and terminates the study 5 hours after turn-on. When running the reference peak value detection loop after turn-on, system controller module **28** activates LED **3** each time a signal peak is detected, and continues doing so for a period of thirty minutes. After termination of the study, a decision integrator module **30** compares the data (describing the number and nature of abnormal muscle activity episodes detected) from episode counter module **26** to a predefined "diagnostic table", stored in decision integrator module **30**, which categorizes all patterns of muscle activity episodes as falling into one of several diagnostic categories. Each diagnostic category corresponds to a particular non-volatile marker **4**. A non-volatile marker **4** corresponding to the diagnostic category identified by the study is then activated by decision integrator module **30**.

In normal operation, the user places device **8** over the appropriate muscle group to be screened and switches the device on by pulling out tab **1**. The user then performs a reference peak value generation maneuver as follows:

- When device **8** is being used to screen for bruxism or clenching, the user clenches his teeth three times as hard as possible, ensuring that LED **3** lights up with each jaw contraction.
- When device **8** is being used to screen for PLMS or RLS, the user lies in bed and extends his big toe as hard as possible three times, ensuring that LED **3** lights up with each muscle contraction.

During the first 30 minutes after device **8** turn-on, CPU **10** runs a loop to identify three distinct maxima in the background EMG pattern (ignoring minor peaks occurring before and after the three distinct maxima generated by the reference peak value generation maneuver), and to integrate these three peaks so as to generate a reference peak value against which all subsequent signals will be compared. During

this period of time the user goes to sleep. 30 minutes after turn-on, device **8** commences sensing and processing EMG signals, and continues to do so for approximately 5 hours. After 5 hours, the total number of abnormal muscle activity episodes (bruxing or PLMS episodes) counted is compared to a lookup table, and a determination is made as to which output flag to activate. When the tibialis anterior muscle is being monitored for the occurrence of PLMS, one of the following output flags is activated:

1. "No problem" flag - no PLMS detected.
2. "Minor problem" flag - average 1-5 PLMS episodes per hour.
3. "Moderate problem" flag - average 6-10 PLMS episodes per hour.
4. "Severe problem" flag - average over 10 PLMS episodes per hour.
5. "Bad study" flag - EMG signals where lost during the study, or were of amplitude greater than 300% of the reference peak value.

When the temporalis or masseter muscles are being monitored for the occurrence of bruxism, one of the following output flags is activated:

1. "No problem" flag – less than 20 bruxism episodes detected over 5 hours.
2. "Minor problem" flag – 21 to 40 bruxism episodes detected over 5 hours.
3. "Severe problem" flag – more than 40 bruxism episodes detected over 5 hours.
4. "Bad study" flag - EMG signals where lost during the study, or were of amplitude greater than 300% of the reference peak value.

A similar lookup table describing the occurrence of clenching, rather than bruxism, may also be incorporated into device **8**.

Upon awakening, the user reads the result of the study. As the markers retain their appearance indefinitely, the device can be kept indefinitely as a medical record, and test results can be compared from study to study.

The average signal amplitude for nocturnal clenching is usually at least 50% greater than the reference peak value (which was measured during maximal voluntary clenching), and the average signal amplitude for bruxism is usually at least 20%

greater than the reference peak value. Thus, masseter or temporalis signals which are between 15% and 40% greater than the reference peak value for more than a minimal duration (such as 0.5 seconds) will be identified as bruxism episodes, and signals which are more than 40% greater than the reference peak value will be identified as clenching episodes.

The average signal amplitude for PLMS is usually at least 30% greater than the reference peak value measured during maximum voluntary toe extension. Thus, tibialis anterior signals which are at least 30% greater than the reference peak value for more than a minimal duration (such as 0.5 seconds) will be identified as abnormal events, and the occurrence of at least 3 such events within 40 seconds will be counted as one PLMS episode. Normal adults usually have less than 5 episodes per hour during sleep.

Figures 4, 5 and 6 describe a preferred embodiment of the display component of device **8**. In this embodiment, each display element **4** is an electro-chemical cell. An electro-chemical reaction occurring in the cell causes a change in appearance of one or more electrodes of the cell. As that electrode is visible to the user, the color change serves to convey information to the user. By varying the shape and number of electrodes, display cells of this type can be constructed so as to convey a wide variety of display messages.

The method of this embodiment of the display component of device **8** is based on electroplating, electro-stripping or otherwise changing the appearance of an electrode in an electro-chemical cell, under the influence of a weak electrical current (a current of only a few micro-Amperes, at a voltage of less than 3V, is sufficient to remove several microns of metal off an area of several square millimeters, and thus create a noticeable color change). The process takes place in a solid gel environment (gel cover **5**). The gel environment consists of a polymeric gel containing electrolytes to facilitate current transfer through the gel and otherwise complete the chemical reaction that needs to take place inside the cell.

Figure 4 is a schematic depiction of a cross-section through an electro-chemical display cell. The display cell comprises a base material **41**, such as a polycarbonate film, onto which a conductive copper layer is laminated. The copper layer can be shaped, using standard Printed Circuit Board (PCB) manufacturing

techniques well known in the art (such as photolythograpy and acid etching), into any desired character or symbol, depending on the nature of the information to be depicted on the display. The copper layer comprises two separate elements - one being a message-bearing element **42**, and the other a current-collecting element **44**. In a typical configuration message-bearing element **42** has dimensions of 2 by 4 mm, and current-collecting element **44** has dimensions of 3 by 12 mm.

Two layers **43** and **45** of an electro-conductive material such as tin (Sn) solder are plated onto copper elements **42** and **44** respectively, using standard PCB manufacturing techniques (such as electroplating or electroless plating), so as to achieve a thickness of layers **43** and **45** of at least 0.1 – 0.5 micrometers. A layer of polymeric conductive gel **46** covers base material **41** and solder layers **43** and **45**. Gel layer **46** is 1-3 mm thick, is a polymer of the PVA family, and contains small amounts of NaCl, KCl and/or other inorganic salts. An optional layer of conductive aluminum foil **47** covers gel layer **46**, and serves to increase the display cell's conductivity.

Activation of the display cell is achieved by applying a low voltage source (approximately 3V DC) across copper elements **42** and **44**. The positive terminal of the voltage source is connected to message-bearing element **42**, and the negative terminal of the voltage source is connected to current-collecting element **44**. Copper elements **42** and **44** thus function as electrodes of an electro-chemical cell, with element **42** being the anode, and element **44** being the cathode of the cell. As electric current begins to flow from element **42** to element **44**, solder layer **43** begins to dissolve into gel layer **46** off of message-bearing element **42**. Initially, over the course of several minutes, the solder of solder layer **43** tarnishes, becoming covered with the black layer of the oxide. Thereafter, once current flow ceases, and depending on the exact composition of gel layer **46**, the oxide dissolves into gel layer **46**, eventually exposing the red color of copper element **42**. If, however, gel layer **46** is removed when current flow ceases, the oxide does not dissolve.

The electrochemical reaction occurring in the display cell is as follows:

At the Anode (+):

$Sn + 2(HO) \rightarrow Sn(HO)_2$ (black solid),

At the Cathode (-):

$2H^+ + 2e- \rightarrow H_2$ (gas)

During this electrochemical process, copper element **44** remains plated by solder layer **45**, thus serving as a reference color enhancing the readability of the color change induced on message-bearing element **42**. Current is then terminated and gel layer **46** removed, so as to expose message-bearing element **42** and allow the user to read the information depicted on the display cell. In this exposed state the cell can be kept indefinitely. Alternatively, if gel layer **46** is transparent and is of such composition that oxide doesn't dissolve into it, then readout can be done and the display kept without removing gel layer **46** off of the display.

In an alternative embodiment of the display component of device **8**, copper element **42** is not initially coated by solder layer **43**, but rather, as current flows from element **42** to **44**, element **42** becomes plated with a conductive material extracted from gel layer **46** in an electroplating process, thereby rendering a color change in element **42**.

FIG. 5 is a schematic depiction of a cross section through the activated display cell after the user has removed gel layer **46**.

FIG. 6 is a line drawing of the external appearance of two electro-chemical display units, as described in the current invention. Two of several possible formats for displaying study outcomes are shown. In FIG. 6A a format suitable for use when a patient, rather than a doctor, will read the study outcome is shown. As illustrated, the display shows that a "moderate" problem had been detected by the device. In FIG. 6B a format suitable for use when a doctor will read the study outcome is shown. As illustrated, the display shows that 52 bruxing episodes had been detected by the device.

The silver colored Sn coating of message-bearing element **42** tarnishes to dark gray after approximately 20 minutes of current flow. Thereafter, if current flow is discontinued, the coating dissolves fully into gel layer **46** over the course of several hours, thus fully exposing the underlying copper of message bearing element **42**. As the red copper color of message bearing element **42** actually provides poorer contrast against the silver-colored coating of element **44** than does the tarnished dark gray color of Sn layer **43**, a small "maintenance current" may be passed though the cell (either as a small DC current, or as pulses with low duty cycle, at approximately 1% of the activation current), so as to prevent the coating from dissolving fully into gel

layer 46. Voltage of this maintenance current may be maintained until the gel layer is peeled off to read the display, or until the battery runs out.

The display cell described above is thus a non-volatile, single use, micro-power, non-erasable display, which may be suitable for any application where very low quantities of information are to be displayed to the user and then kept permanently as a record of the result. Display cells of this nature could thus be used in multiple monitoring devices, such as devices used to monitor acceleration or temperature of a cargo shipment (so as to determine if the shipment had been exposed to shock or high temperatures while in transit), and medical devices in which the user is informed of a negative or positive test result. Electro-chemical displays of the type described in the current invention overcome drawbacks of existing display technologies such as LED and LCD displays (which require ongoing power to operate) and electro-mechanical flags (which are relatively big and heavy, and are limited to the display of only one or two bits of data).

It will be appreciated that the invention as described herein may be supplemented in several ways, without departing from the spirit of the invention. For example, a heat sensitive element, to sense skin temperature during the study, may be incorporated into device 8. This element would indicate if the device had been removed during the night, prior to the end of the study. In addition, a light sensor may be incorporated into device 8 so as to determine that the lights were switched off during the study, as a fraud detection mechanism. A further addition to device 8 may be a circuit and appropriate software that monitor the DC resistance between electrodes 7 and 9. With placement of electrodes 7 and 9 on the skin of the user the circuit is completed, inducing flow of a small current. Such a circuit can therefore be used to automatically switch on the electronic components of device 8, when a current of over a predefined minimum is detected. This would eliminate the need to manually turn on device 8 by pulling tab 1. The same circuit can also be used to detect if device 8 was removed, or if the skin contact of electrodes 7 and 9 was intermittent or defective, during the study.

It will be further appreciated that the technique of integrating a minimal data analysis system onto a sensor, such that sensed data is analyzed in real time, and an easily understood study report is immediately generated (as described in the current

invention with regard to the sensing of abnormal nocturnal muscle activity), can be applied to screening devices for a variety of medical conditions. Some examples of possible monitoring devices which share this technique of data analysis and explication, but which sense different physiological parameters, are:

1. A nocturnal tremor sensor, which could aid in the titration of anti-tremor medication in patients with Parkinsons disease or other neuro-motor disorders.
2. A sensor for the detection of sweat during the night, which could aid in the titration of medication for night sweating, and help diagnose and treat night sweating due to hormone deficiency, night terrors, diabetes, or other reasons.
3. A night breath-sounds monitor, or nocturnal cough counter, for asthma management.
4. A sensor for the detection of body temperature during the night, which could aid in the titration of medication for menopausal heat flashes.
5. A sensor for the detection of breathing movements, which could aid in the long term follow up of asthma by counting total movements during a set period.
6. A sensor for the detection of gross body movement during the night, to help in the long term treatment and follow up of syndromes such as head banging and body rocking.
7. A sensor for the detection of bladder muscle activity, to help diagnose and titrate medications for "Detrusor muscle instability" in women.

All the above mentioned applications of the current invention are intended for use as screening modalities, rather than as definitive diagnostic tests for the relevant illnesses.

There has thus been described a nocturnal muscle activity disorder screening system which can be easily and reliably used without the need for professional supervision or the use of complex data storage and analysis hardware. The system is sufficiently simple and inexpensive as to facilitate performance of multiple studies on the same patient, on unreliable patents, or on patients with a low likelihood of having real pathology. The system allows the study to be performed in the patients natural sleep environment, and does not infringe patient privacy.

WHAT IS CLAIMED IS:

1. A muscle activity monitoring system, comprising

a) a muscle activity sensor, for sensing muscle activity at a location on a body;

b) a processor, for analyzing said sensed muscle activity to determine the presence of a pattern of muscle activity, and for correlating said pattern of muscle activity with a diagnosis;

c) a display, for displaying said diagnosis;

d) a power source, for powering said muscle activity sensor, said processor, and said display; and

e) a housing, for housing said processor, said display, and said power source, on said muscle activity sensor, said housing being placeable at said location on said body.

2. The system of claim 1, wherein said muscle activity sensor includes an electromyograh electrode.

3. The system of claim 2, wherein said pattern of muscle activity is a frequency of electromyographic signals of amplitude greater than a reference amplitude.

4. The system of claim 1, wherein said location is selected from the group comprising the location of the temporalis muscle, the location of the masseter muscle and the location of the tibialis anterior muscle.

5. The system of claim 1, wherein said diagnosis is selected from the group comprising a degree of severity of bruxism, a degree of severity of restless leg syndrome, and a degree of severity of paroxysmal leg movement syndrome.

6. The system of claim 1, wherein said power source is a battery.

7. The system of claim 1, wherein said display is selected from the group comprising heat-sensitive permanent color display elements and electro-chemical permanent color display elements.

8. The system of claim 1, wherein said housing is a flexible plastic unit.

9. The system of claim 1, wherein said processor comprises

a) an analog to digital converter, for converting a signal describing said sensed muscle activity into a digital signal;

b) an envelope detector, for detecting signals, in said digital signal, describing episodes of muscle activity;

c) a valid muscle contraction detector, for determining a reference amplitude for said detected signals describing episodes of muscle activity, and for comparing said detected signals describing episodes of muscle activity to said reference amplitude so as to detect episodes of potentially abnormal muscle contraction;

d) a reference peak memory, for storing said reference amplitude;

e) an episode detector, for detecting episodes of abnormal muscle contraction by calculating a temporal relationship between said episodes of potentially abnormal muscle contraction and by counting said episodes of potentially abnormal muscle contraction;

f) an epidode counter, for counting said detected episodes of abnormal muscle contraction;

g) a decision integrator, for

i) generating a description of a pattern of muscle activity from said counted detected episodes of abnormal muscle contraction,

ii) correlating said described pattern of muscle activity with a diagnosis, and

iii) informing said display to display said diagnosis, and

h) a system controller, for initiating and terminating operation of said analog to digital converter, said envelope detector, said valid muscle contraction detector, said reference peak memory, said episode detector, said episode counter, and said decision integrator.

10. A muscle activity monitoring method, comprising the steps of

a) placing a housing at a location on a body;

b) sensing muscle activity at said housing during a time interval;

c) processing said sensed muscle activity to detect a pattern of muscle activity, said processing occurring during said time interval;

d) correlating said pattern of muscle activity with a diagnosis, said correlating occurring during said time interval; and

e) displaying said diagnosis on said housing.

11. The method of claim 10, wherein said location is selected from the group comprising a location of the temporalis muscle, a location of the masseter muscle and a location of the tibialis anterior muscle.

12. The method of claim 10, wherein said muscle activity is sensed as an electromyographic signal.

13. The method of claim 10, wherein said processing and said correlating are achieved by a processor located on said housing.

14. The method of claim 10, wherein said displaying is achieved by inducing a permanent color change in a display element on said housing.

15. The method of claim 10, wherein said housing is a flexible plastic unit.

16. An electrochemical display system, comprising

a) a first electrode;

b) a second electrode, and

c) a layer of electro-conductive material covering at least part of one of said electrodes, said layer being operative to undergo an electrochemical process when electric current flows from one of said electrodes to the other of said electrodes, and wherein said electrochemical process eventuates in a change in a perceived color of one of said electrodes.

17. The electrochemical display system of claim 16, wherein one of said electrodes includes copper.

18. The electrochemical display system of claim 16, wherein said electro-conductive material includes a material selected from the group comprising tin and solder.

19. The electrochemical display system of claim 16, wherein said electrochemical process includes electrolysis.

20. The electrochemical display system of claim 16, further comprising

d) a layer of electro-conductive gel at least partially covering said electrodes and said conductive layer.

21. The electrochemical display system of claim 20, wherein said electro-conductive gel includes a polymeric gel containing inorganic salts.

22. A method of irreversible display, comprising

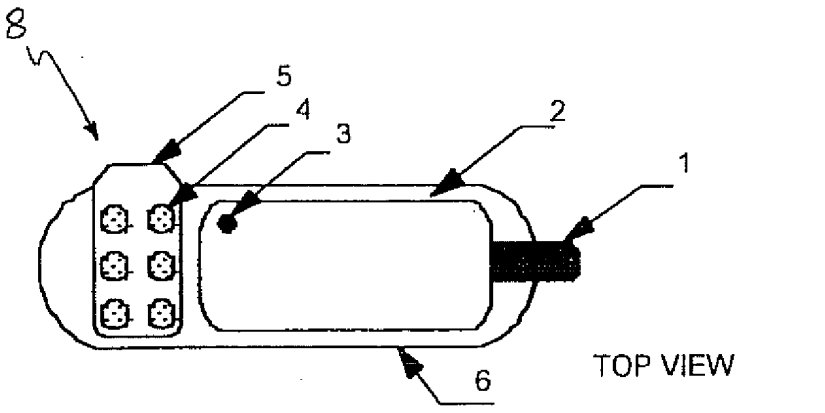
a) providing a plurality of electrodes, at least one of said

electrodes being at least partially covered by an electro-conductive material;

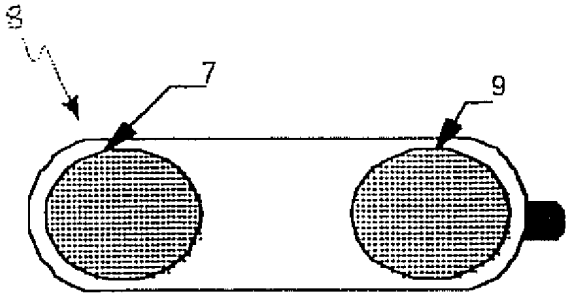
b) inducing a flow of electrical current between said electrodes, thereby effecting an electrochemical process in said electro-conductive material, and thereby causing a change in a perceived color of said least one of said electrodes being at least partially covered by said electro-conductive material.

23. The method of claim 22, wherein said electrochemical process includes electrolysis.

FIGURE 1

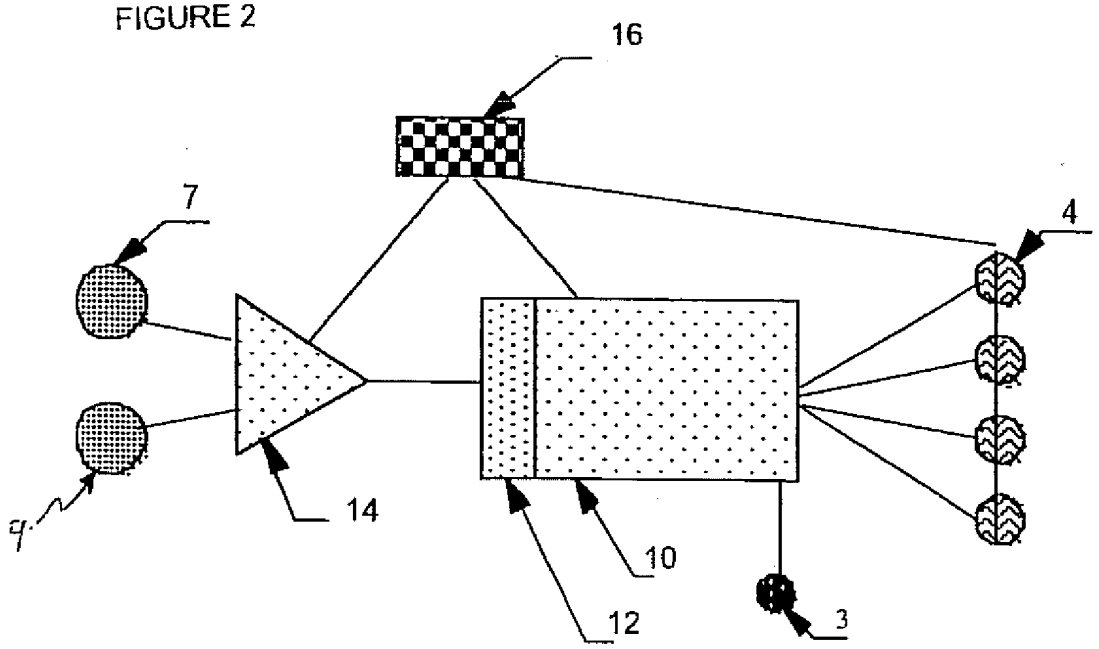


TOP VIEW



BOTTOM VIEW

FIGURE 2



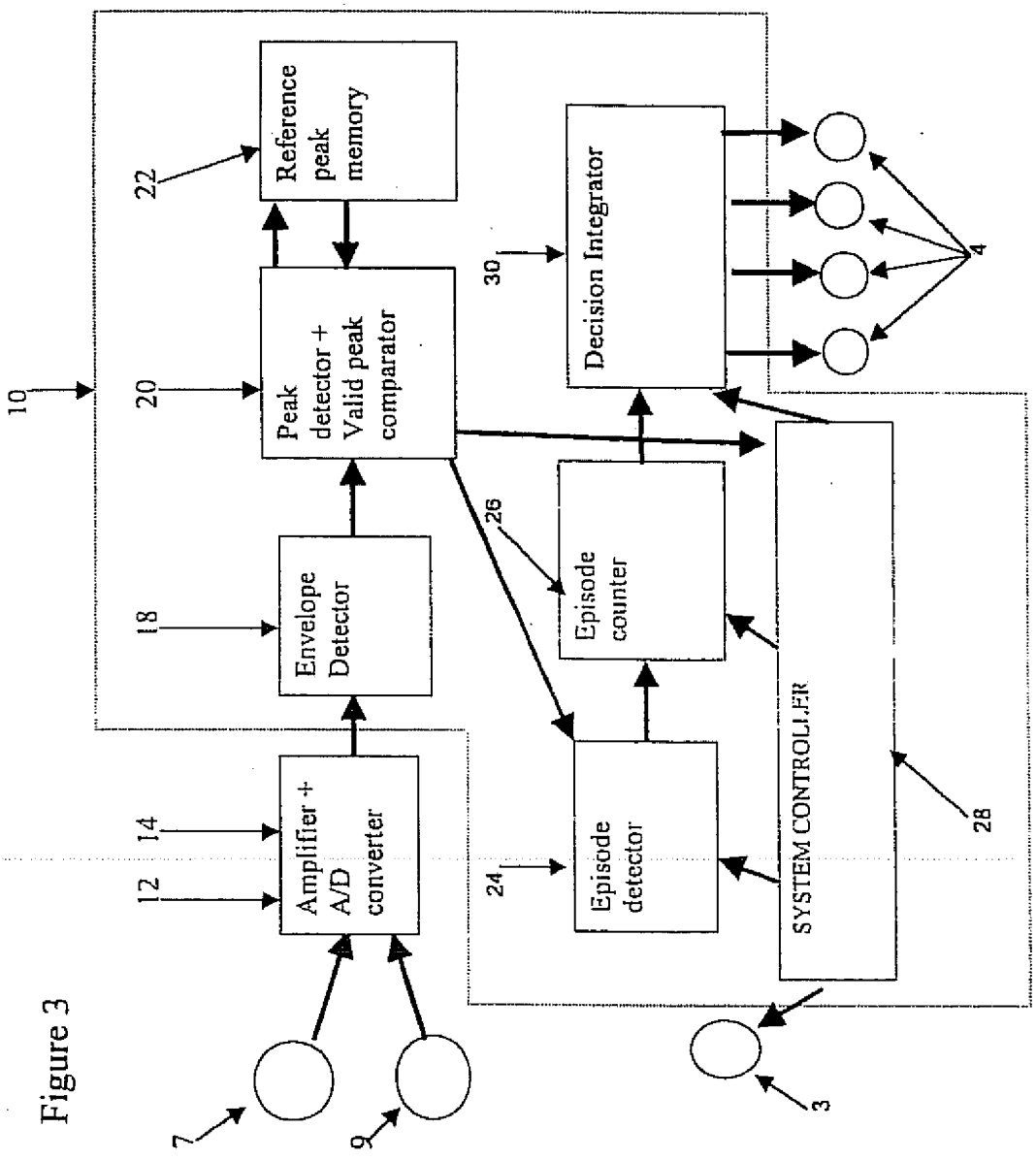

10
20
Peak detector + Valid peak comparator
22
Reference peak memory
30
Decision Integrator
4
18
Envelope Detector
26
Episode counter
12
14
Amplifier + A/D converter
24
Episode detector
SYSTEM CONTROLLER
28
7
9
3

Figure 3

FIGURE 4

Unactivated cell

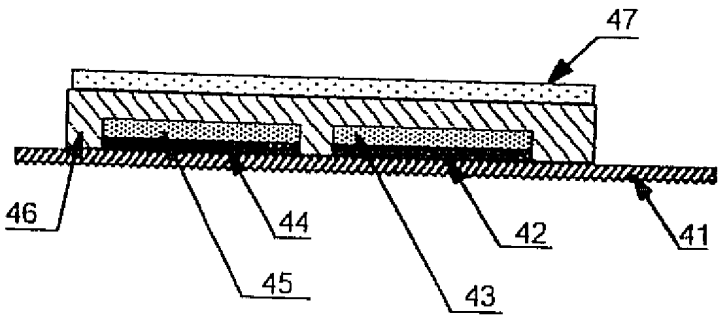


FIGURE 5

Activated cell

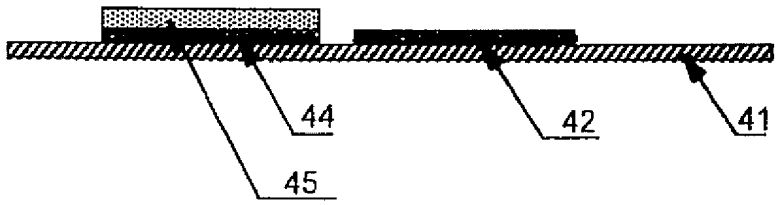
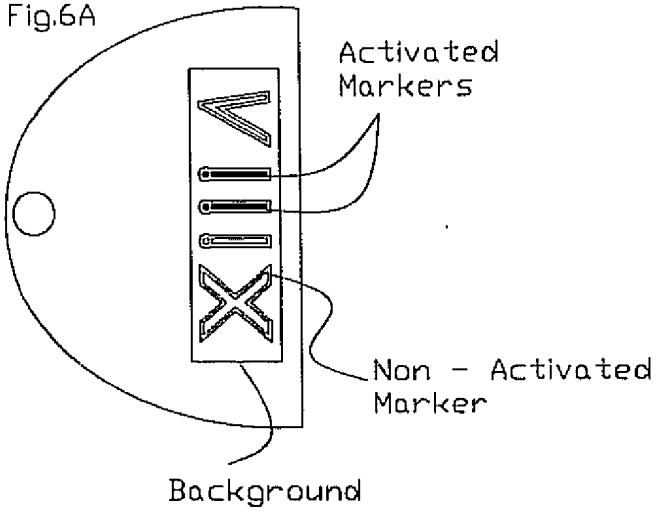


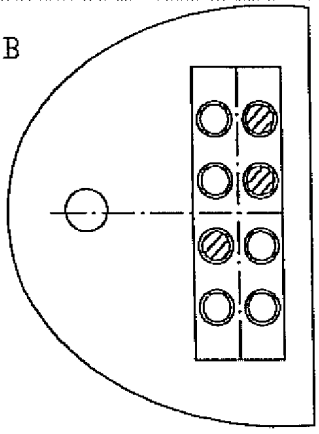
Fig.6A



Patient Display
√ = no problem
| = mild problem
|| = moderate problem
||| = severe problem
X = bad study

C13:11

Fig.6B



Doctors Display:
number of apnea episodes shown in 8 bit binary code

Key:

1 O	⊘16
2 O	⊘32
4 ⊘	O64
8 O	O128

Here the number of opnea episodes is

4+16+32=52